QA-604– Equipment Registration, Maintenance, and Calibration

1. **PURPOSE:**
   To ensure that equipment used in clinical research for generation, measurement, or assessment of research data is adequately registered (tagged), maintained, and calibrated.

2. **SCOPE:**
   This SOP applies to equipment used for clinical research purposes regardless of how the equipment is obtained (i.e., sponsor provided, purchased with research/internal funds, or equipment used in the health care environment for research purposes).

3. **RESPONSIBLE INDIVIDUALS:**
   It is the responsibility of the Principal Investigator (PI) and research team to know how and where equipment, and records related to equipment, are maintained.

4. **RELATED TERMS AND CONDITIONS:**
   Please reference the Standard Operating Procedures Glossary of Terms for complete definitions of terms in this SOP.

5. **POLICY STATEMENT:**
   This SOP applies to equipment used for clinical research purposes.

6. **PROCEDURES:**
   6.1 All equipment must be tagged and properly maintained and cleaned after each use.
   6.2 If the equipment is provided by a sponsor and the sponsor does not provide a tag and calibration services, UTRGV facilities or an outside vendor may be used. Note – this is important to discuss during the budget negotiations and site qualification visits.
   6.2 Equipment requiring calibration should be carried out by a licensed subcontractor, the appropriate facility personnel, or designated staff.
   6.3 Calibration/certification is documented by a written label with date affixed to the equipment.
   6.4 Any equipment found to have an outdated calibration/certification label will be reported to the department manager and research manager immediately.
   6.5 Equipment with Past Due Calibration or Routine Maintenance

The department manager and research manager are responsible for either removing the equipment from service or, if the equipment is unique and must remain in service until recalibration/re-certification takes place, affixing a label to the equipment stating that this equipment is outside its date of calibration/certification and may result in the generation of inaccurate data. If research using this equipment is sponsored, the sponsor must be notified in a timely manner.

6.6 Malfunctioning Equipment
The department manager and research manager are responsible for removing the equipment from service and labelling the equipment in a way that makes it clear it should not be used. If research using this equipment is sponsored, the sponsor must be notified in a timely manner for return.

- Sponsor provided equipment is the responsibility of the sponsor.

6.7 Original documents/certificates of equipment inspections, calibrations, maintenance, or other equipment related materials provided by outside vendors are maintained by the department manager and research manager.

6.8 Any studies that use Florence for regulatory purposes must also upload calibration records into the appropriate credentialing binder for their department. If unsure of the appropriate credentialing binder, contact clinicalresearch@utrgv.edu.

7. REFERENCES:

8. FORMS OR ATTACHMENTS:

None