UNIVERSITY OF SOUTH ALABAMA

# CT-107 Equipment Maintenance and Calibration

EFFECTIVE DATE: April 2024

## Purpose

The purpose of this SOP is to ensure that equipment used in the USA Clinical Trials Office (CTO) for the generation, measurement, or assessment of research data is adequately inspected, cleaned and maintained.

## Scope

This policy applies to all equipment used by the USA Clinical Trials Office (CTO) for clinical research purposes.

## Definitions

**Equipment**: Devices used to gather research data, including but not limited to centrifuge, blood pressure monitors, scales, temperature monitoring devices, and EKG machine. Investigational Devices are not considered equipment.

**Calibration**: Process of determining the relation between the output or response of a measuring instrument and the value of the input. Calibration typically involves the use of a measuring standard.

**Maintenance**: Functions or actions required to ensure the proper working order of a piece of equipment. These actions include, but are not limited to, cleaning, minor repairs, changes of tubing, lubricants and other consumable parts, checks for damaged or worn components, and protective measures. Documentation of maintenance by approved vendors is also performed.

## Policy

All CTO staff are responsible for proper use and handling when using equipment for research studies. All equipment should be appropriately cleaned, maintained in good working order, and available for use as needed. All equipment malfunctions should be reported to applicable parties immediately.

All staff are responsible for ensuring that calibration and maintenance occurs according to the below procedures and for retaining appropriate documentation for specified equipment.

Refrigerators and freezers used to store investigational product or samples will not be individually calibrated. Rather, a temperature monitoring probe is used to monitor temperatures. This probe will be calibrated and is subject to this policy.

## Procedure

### Equipment owned by the Clinical Trials Office

1. Calibration of the equipment should be performed prior to the equipment's first use.
2. Documentation of the calibration should be stored in the site's files and made accessible to any outside third party or regulatory body.
3. Research personnel who utilize equipment should inspect for damage or safety concerns prior to each use.
4. Equipment should be calibrated annually with a new calibration certificate on file.
5. Research personnel should clean each item after use to ensure efficiency and longevity of equipment.

### Equipment owned by another department or by USA Hospital Systems

1. Equipment owned by another University of South Alabama department is inspected and calibrated per their internal policies.
2. CTO staff should ensure a label is affixed to the equipment prior to use, indicating the equipment has been approved for use.
3. If equipment is not calibrated or calibration is expired:
    a. Leadership of the department should be made aware.
    b. Equipment should not be used if calibration is not performed or is not current.
4. Research personnel who utilize equipment should inspect for damage or safety concerns prior to use.
5. The department is responsible for its own equipment receipt, storage, preservation, record keeping, physical control, inventory, and disposal documentation.
6. Research personnel should clean each item after use to ensure efficiency and longevity of equipment.

### Equipment owned by the sponsor or contract research organization

1. Any instructions for use sent by the sponsor or contract research organization (CRO) should be maintained on the site level.

2. Before initial use, the study coordinator should ensure equipment does not transmit any protected health information. Any records that contain identifiers should be de-identified prior to transmission.
3. Calibration of equipment supplied for a particular study is the responsibility of the sponsor and/or CRO. Calibration records can be maintained at sponsor level.

## History

**Next Review Date:** April 2027

## Responsible Party

Director, Clinical Trials Office