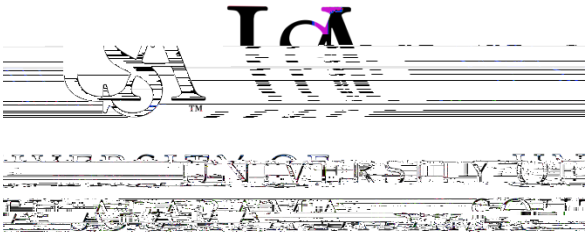

CT-107 Equipment Maintenance and Calibration

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

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