PURPOSE: The purpose of this SOP is to ensure that equipment used in the CRC for the generation, measurement, or assessment of research data is adequately inspected, cleaned and maintained.

SCOPE: This SOP applies all of the instruments and equipment used in the CRC for clinical research purposes.

RESPONSIBILITIES: Research personnel are responsible for using proper care of CRC equipment and for reporting any equipment malfunctions to the CRC Manager immediately. The CRC Manager is responsible for the following:

- Ensure that all equipment is appropriately cleaned, maintained in good working order, and available for research personnel as requested.
- Ensure that written validation reports for new and modified equipment are received from the licensed contractor within 30 days of inspection.
- Maintain written records of all CRC equipment inspections, calibrations, maintenance, and non-routine repairs. These records should include the equipment's serial number, date of procedure, type of procedure, who the procedure performed by, and date of next scheduled procedure

DEFINITIONS:

Equipment: Refers to fixtures, and other tangible property of a non-consumable and non-expendable nature. May also be referred to as assets, items or property

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.

National Institute of Standards and Technology (NIST): A non-regulatory federal agency within the U.S. Department of Commerce whose mission is to promote U.S. innovation and industrial competitiveness by advancing measurement science, standards, and technology in ways that enhance economic security and improve our quality of life.

PROCEDURE:

1. Research personnel who utilize CRC equipment will inspect each item prior to use and clean each item after use to ensure efficiency and longevity of equipment.

2. The CRC Manager will ensure that applicable assets have an identification number assigned to them. The bar code label with readable number will be placed on the item and physically inventoried by the USF System Property Staff annually.

3. The CRC Manager will ensure that all equipment used in the CRC for clinical research studies will be tested, calibrated and/or standardized and approved by a licensed contractor. This calibration will be documented on a written label affixed to each piece of equipment.

4. The CRC Manager will ensure that all equipment requiring calibration will be calibrated against traceable certified equipment (e.g., National Institute of Standards and Technology (NIST)) or a new or recently certified unit that can be traceable to a NIST standard as a reference and documented with a certificate outlining the traceability, test, and results.

5. In the event of equipment failure or malfunction, the CRC Manager will contact a licensed contractor for repairs, and these repairs will be documented in writing. Following repairs, the equipment will be re-calibrated and/or standardized as needed, and documented by a written label affixed to the equipment.

6. Research staff will report any equipment found to have an outdated calibration/inspection label to the CRC Manager immediately.

    6.1. The CRC Manager is responsible for either removing the equipment from service (preferable action) or if the equipment is unique and must remain in service until re-calibration/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.

    6.2. For equipment failure or malfunction that is used for a study, the CRC Manager will notify the study PI and study coordinator to explain the problem, how the problem was discovered, the date equipment was removed from service, the remedial action taken, date re-calibrated/re-certified, date placed back into service.

PROCEDURE (cont.):

7. The CRC Manager will maintain written records in the Calibration and Temperature Log Binder in the CRC work area. The records will contain dates of equipment inspections, maintenance, testing, calibration and/or standardizing procedures, and the person performing the procedure. .

   7.1. He/she will document all routine and non-routine procedures performed on equipment on the CRC Equipment Log (Appendix KK).

   7.2. He/ She will request calibration verification certificates for each item calibrated within 30 days of operational testing date.

8. The CRC Manager will submit equipment records to the OCR for archiving when needed.

9. Departments will be responsible for the care, maintenance, and use of all equipment in their custody.
   - For equipment acquired under grants and contracts, the PI should be aware of any specific equipment care and maintenance requirements defined in the grant or contract.
   - The department is responsible for its own equipment receipt, storage, preservation, record keeping, physical control, inventory, and disposal documentation.
   - A maintenance record must be kept for federally funded equipment. The PI is responsible to care for property entrusted to his or her possession or supervision, and to keep it safe.
   - Care and maintenance includes periodic inspection, regularly scheduled lubrication, protection from exposure, and proper cleaning prior to storage.

REFERENCES:	ICH GCP 4.6.4 21 CFR Part 58: Good Laboratory Practices for nonclinical Laboratory Studies
RELATED POLICIES:	
APPENDICES:	Appendix KK: CRC Equipment Log
REVISION HISTORY: Keep a running history of all revision dates.	

Effective Date	Review Date	Revision Date
01/01/2015	01/01/2015	06/15/2016