

	POLICY TITLE: Equipment Maintenance
MANUAL NAME: Clinical Operations	POLICY NUMBER: CR 2.0.2 <input type="checkbox"/> Addendum to Corporate Policy <input type="checkbox"/> Form Available In I-REPP System
SECTION (as applicable): Clinical Research	POLICY OWNER: Tedd Adair, Vice President of Clinical Operations and Chief Clinical Officer
ORIGINATION DATE: 01/01/2011	FINAL APPROVAL DATE: April 30, 2016

POLICY:

When performing maintenance and calibration of study-related equipment, to ensure the validity of data collected during clinical trials by keeping all study-related equipment maintained and calibrated properly.

SCOPE:

This procedure applies to all study-related equipment owned by IASIS facility and in use for any study conducted at an IASIS facility.

DEFINITIONS:

Not Applicable

PROCEDURE:

Study-Related Equipment:

Study-related equipment refers to any equipment used during a study that affects the validity of the data collected. Examples of study-related equipment include, but are not limited to, the following:

- centrifuge
- blood pressure monitor
- EKG/ECG machine
- thermometer
- scale
- temperature and/or humidity monitors
- Point-of-Care devices

Maintenance and Calibration:

For all study-related equipment, the following procedures are followed:

- Equipment is maintained according to manufacturer’s recommendations.
- Equipment is calibrated according to one of the following schedules, whichever is more frequent:
 - o Frequency that is recommended by the manufacturer
 - o Annually
- A NIST certificate of calibration, if available, is obtained for all equipment at least annually.
- The above maintenance and calibration activities are documented using the *Equipment Maintenance/Calibration Log* form.

Responsibility:

- The study coordinator is responsible for ensuring that all of the above procedures are followed for relevant equipment used in any study he/she is coordinating.

FORM REFERENCES:

Not Applicable

REFERENCES:

Not Applicable

Review/Revised Date:	Title:	Description of Change or Location of Change in Document:
04/30/2016	Tedd Adair VP Clinical Operations & CCO	Scheduled review; converted to ISO Policy Template

EQUIPMENT MAINTENANCE/CALIBRATION LOG

Equipment Type: _____
 Manufacturer: _____
 Model #: _____

Manufacturer's maintenance/calibration recommendations, including *what activities* should be performed and the *frequency* of these activities (list or attach to this form):

Maintenance/Calibration Activities Performed	Performed by & Date Performed	Documentation (must have at least one form of documentation)
Activity: _____ _____	Name: _____ Date: ___/___/___	<input type="checkbox"/> Signature: _____ <input type="checkbox"/> Attached to this form <input type="checkbox"/> Attached to equipment
Activity: _____ _____	Name: _____ Date: ___/___/___	<input type="checkbox"/> Signature: _____ <input type="checkbox"/> Attached to this form <input type="checkbox"/> Attached to equipment
Activity: _____ _____	Name: _____ Date: ___/___/___	<input type="checkbox"/> Signature: _____ <input type="checkbox"/> Attached to this form <input type="checkbox"/> Attached to equipment
Activity: _____ _____	Name: _____ Date: ___/___/___	<input type="checkbox"/> Signature: _____ <input type="checkbox"/> Attached to this form <input type="checkbox"/> Attached to equipment
Activity: _____ _____	Name: _____ Date: ___/___/___	<input type="checkbox"/> Signature: _____ <input type="checkbox"/> Attached to this form <input type="checkbox"/> Attached to equipment
Activity: _____ _____	Name: _____ Date: ___/___/___	<input type="checkbox"/> Signature: _____ <input type="checkbox"/> Attached to this form <input type="checkbox"/> Attached to equipment
Activity: _____ _____	Name: _____ Date: ___/___/___	<input type="checkbox"/> Signature: _____ <input type="checkbox"/> Attached to this form <input type="checkbox"/> Attached to equipment
Activity: _____ _____	Name: _____ Date: ___/___/___	<input type="checkbox"/> Signature: _____ <input type="checkbox"/> Attached to this form

		<input type="checkbox"/> Attached to equipment
Activity: _____ _____	Name: _____	<input type="checkbox"/> Signature: _____
_____	Date: ___/___/___	<input type="checkbox"/> Attached to this form <input type="checkbox"/> Attached to equipment