
SOP Number ADM-005-01
SOP Name Electrical Safety Testing of Research Equipment SOP
Effective Date 01/MAR/2012

1.0 SCOPE

- 1.1 This SOP applies to any and all research activity involving University and non-University Hospital medical devices/equipment that are used at University Hospital, including any outpatient or inpatient setting for which the facility, resources, or personnel are owned, leased to, or managed in part or in whole by University Hospital.
- 1.2 Covered research may involve patients, persons who are not registered patients, staff, facilities or resources, human tissue or samples, and identified or de-identified data.

2.0 PURPOSE

- 2.1 The purpose of this SOP is to provide guidance to the research team and University Hospital employees concerning the use of University Hospital and non-University Hospital devices/equipment during research activities. This policy is intended to improve the safety of patients and hospital infrastructure.

3.0 DEFINITIONS

- 3.1 None

4.0 PROCEDURES

- 4.1 Any of the following electrical devices used for research need to be registered with an approval for use by Clinical Engineering:
- Any electrical device that touches a patient
 - Any device that is plugged into an electrical outlet
- 4.2 The Principal Investigator (or designee) is responsible for notifying Clinical Engineering and arranging for equipment evaluation and approval prior to first use.
- 4.3 Devices can be submitted to Clinical Engineering for approval by phone at 513-585-5800 or by email at research-clineng@uchealth.com.
- 4.4 Clinical Engineering must be informed of the following:
- Name of the item
 - Purpose of the item
 - Person using the item
 - Role of the study
 - Place where item will be stored (e.g. Research Office or University Hospital)

5.0 LIST OF ATTACHED FORMS

- 5.1 None

6.0 REFERENCES

- 6.1 None

7.0 APPROVAL

Signature on file
VP of UC HEALTH RESEARCH OR DESIGNEE

14/FEB/2012
DATE