
SOP Number ADM-004-01
SOP Name Continuation of Investigational Drug, Device or Biologic in Patients Encountered in an Inpatient Facility who are on Research Protocols SOP
Effective Date 01/MAR/2012

1.0 SCOPE

1.1 This procedure applies to any and all research with an investigational drug, device or biologic involving UC Health, including research conducted in any outpatient or inpatient setting for which the facility, resources, or personnel are owned, leased to or managed in part or in whole by UC Health.

2.0 PURPOSE

2.1 To provide guidance (to investigators, research team members, UC Health employees, and any employee of a UC Health facility) regarding the continuation by clinical providers of investigational drug, device or biologic for patients who are actively enrolled in research protocols.

3.0 DEFINITIONS

3.1 **Investigational drug, device or biologic:** A drug, device or biologic agent used in human research study for the primary intent of accumulating scientific knowledge. This includes:

- All drugs, devices or biologics not approved by the FDA
- FDA approved drugs, devices or biologics used to accumulate scientific knowledge
- Any substance placed into the body for research purposes (e.g. IV contrast dye for a CT scan that would not be ordered were it not for the research protocol)

4.0 PROCEDURES

4.1 If a patient who is on an investigational drug, device or biologic is admitted to a UC Health hospital facility, the treating physician and principal investigator or designee shall refer to UC Health Investigational Drug Services Policy UCH-RX-MED MGMT-010-03 which can be accessed by contacting the Investigational Drug Services of UC Health.

4.2 The treating physician should make a decision regarding continuation of the investigational drug, device or biologic in collaboration with the principal investigator and/or research team designee.

5.0 LIST OF ATTACHED FORMS

5.1 None

6.0 REFERENCES

6.1 UC Health Investigational Drug Services Policy UCH-RX-MED MGMT-010-03

7.0 APPROVAL

Signature on file
VP of UC HEALTH RESEARCH OR DESIGNEE

14/FEB/2012
DATE