LOYOLA UNIVERSITY HEALTH SYSTEM

LOYOLA UNIVERSITY CHICAGO

Management of Research Equipment in LUMC
PRO-005
Effective date: 10-April-2018

I. SCOPE

Equipment and supplies to be utilized for clinical research that:

- Are brought into Loyola University Medical Center (LUMC) specifically for the conduct of clinical research (new equipment or supplies). These include but are not limited to non-medical equipment that will interface with LUMC networks or equipment.
- Are already owned or leased by LUMC and will be modified via hardware or software for a clinical research study (modification of existing equipment or supplies).

This SOP is complementary to SOP PRO-001 Investigational Device Storage and Accountability and supports implementation of Policy CR-002 Operational Assessment of Research Policy.

II. Definitions

"Medical Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes (The Joint Commission Comprehensive Accreditation Manual, Hospital Glossary, version July 1, 2017).

  All Medical Devices meet the definition of Medical Equipment.

"Medical Equipment" means fixed and portable equipment used for the diagnosis, treatment, monitoring, and direct care of individuals. (The Joint Commission Comprehensive Accreditation Manual, Hospital Glossary, version July 1, 2017)

"Medical Supplies" means medical items, usually of a disposable nature, such as bandages, sterile drapes, and suture materials. These supplies differ from permanent or durable items, such as medical equipment and devices. (The Joint Commission Comprehensive Accreditation Manual, Hospital Glossary, version July 1, 2017)

"Significant risk device" is an investigational device that: (1) is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject; (2) is for use in supporting or sustaining human life and represents a potential for serious risk to the health, safety, or welfare of a subject; (3) is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or (4) otherwise presents a potential for serious risk to a subject. (21 CFR 812)

III. PROCEDURES

A. Process

1. When a new research study is submitted via the Research Channel, a designated colleague in the LUMC Clinical Research department ("LUMC CR") requests the Principal Investigator and/or his/her designee ("Study Team") team provide a list of equipment and supplies to be provided for the research study or to be modified for the conduct of the study at LUMC.

2. **For new equipment and supplies:**
   a. LUMC CR works with the Study Team to determine which institution will manage the equipment or supplies. Equipment and supplies will be controlled by LUMC unless all the following apply:
      (1) It is not a significant risk device
      (2) It does not require special disinfection and therefore may be effectively disinfected before patient use by the Study Team
      (3) It is operated by LUC employees only, including dual LUMC/LUC employees
      (4) It is not purchased by LUMC
      (5) It does not require connection to LUMC's secure internet
      If all criteria are met, the equipment may be managed by LUC.
   b. The LUMC Director of Clinical Engineering will be consulted if needed to determine which institution should control the equipment.
   c. LUMC CR informs the LUC and LUMC contract negotiators of the equipment and supplies to be controlled by LUMC and to be controlled by LUC. If LUMC is to purchase equipment, LUMC CR will request the Purchase Addendum template from the LUMC Office of the General Counsel.
   d. LUMC CR informs the LUMC Risk/Insurance Manager (Tel. 708-538-4532) of the equipment to be used in LUMC. The LUMC Risk/Insurance Manager will inform LUMC CR if additional information is needed for his/her assessment, and what controls or approvals are needed.
   e. LUMC CR facilitates LUMC Information Technology (IT) review (see Section C).
   f. If the equipment or supplies are controlled by LUMC:
      (1) LUMC CR is responsible for understanding the storage and security obligations for control of the equipment as dictated by the equipment's Instructions for Use (IFU) and the contract, including limiting use of the equipment to the Study Team.
      (2) LUMC CR contacts the administrative director or designee of the clinical areas in which the equipment will be used to document a plan to meet the obligations for control of the equipment, and ready access to the equipment's instruction booklet.
      (3) If the equipment shows evidence of breakage, compromised storage, tampering, defects, or malfunctioning:
         (a) LUMC CR or employee of the clinical area, whoever identifies the potential defect first, removes the equipment from service, labels the equipment "Do not use", and notifies LUMC Clinical Engineering.
         (b) The clinical area notifies LUMC CR, and LUMC CR notifies the Study Team immediately.
         (c) The Study Team notifies the supplier immediately for additional instructions.

(4) LUMC CR is responsible for requesting new charge codes or disseminating coding guidance as necessary to ensure correct billing for devices that will generate a charge.
(5) LUMC CR, with the assistance of the Study Team, is responsible for confirming the sponsor will provide training on, customer support for, and maintenance of sponsor-loaned equipment.
(6) If the equipment will be operated by LUMC employees, LUMC CR is responsible for ensuring documentation of competency meets LUMC requirements.
(7) LUMC CR and the Study Team are responsible for following LUMC Supply Chain requirements (see Section D).
(8) LUMC CR is responsible for following LUMC Clinical Engineering requirements (see Section B).
(9) LUMC CR is responsible for returning equipment and supplies as directed by the sponsor and the contract.

g. If the equipment or supplies are managed by LUC:
(1) The Study Team is responsible for understanding the storage and security obligations for control of the equipment as dictated by the equipment's Instructions for Use (IFU) and the contract, including limiting use of the equipment to study purposes.
(2) The Study Team is responsible for ensuring items are disinfected according the manufacturer's IFU before use with LUMC patients.
(3) The Study Team is responsible for ensuring items are not expired before use with LUMC patients.
(4) The Study Team is responsible for confirming the sponsor will provide training on, customer support for, and maintenance of sponsor-loaned equipment and facilitates these activities with the sponsor.
(5) The Study Team is responsible for arranging the ordering, shipping, and storage of items.
(6) The Study Team is responsible for following LUMC Clinical Engineering requirements (see Section B).
(7) The Study Team is responsible for returning equipment and supplies as directed by the sponsor and the contract.

h. The individual(s) operating the equipment or supplies, be they LUMC employees or Study Team members, must notify the LUMC Office of Patient Safety/Risk Management immediately if the equipment or supplies are suspected of causing harm to a patient, visitor, employee, or staff member. The individual must sequester the suspect equipment/ supplies (including any attachments, components, cables, accessories, packaging, etc.) and label "Do not use". They may not be returned to the equipment manufacturer/vendor/sponsor until authorized by LUMC Risk Management.

3. **For modification of existing equipment and supplies:**
a. LUMC CR works with the Study Team to clarify the scope of the proposed modification.
b. LUMC CR obtains approval to modify the equipment from the administrative director with oversight of the equipment.
c. If the administrative director approves, LUMC CR sends a summary of the proposed modification to the LUMC Director of Clinical Engineering. The Director:

(1) Assesses the impact of the modification on the equipment's purchase agreement and corresponding service or maintenance agreement
(2) Provides guidance on the contractual controls needed before the modification may occur.

d. LUMC CR ensures LUMC's Office of the General Counsel, Risk Management, and Supply Chain approve contractual controls.

4. LUMC CR and the Study Team work collaboratively to ensure effective communication between stakeholders (sponsor, Study Team, LUMC CR, LUMC departments).

B. **Clinical Engineering Requirements**

1. All equipment to be used in LUMC must undergo an Incoming Safety Inspection.
   a. The individual responsible for the equipment calls LUMC Clinical Engineering at 6-5555 to schedule the inspection. The inspection must be completed before the equipment is used with a patient.
   b. If the equipment will be on site for more than 6 months, inform LUMC Clinical Engineering. They will put a non-facility-owned tag on it.
   c. If the equipment is altered after the Incoming Safety Inspection, another inspection is needed.
2. If it is unclear if the equipment requires LUMC Clinical Engineering inspection, LUMC CR sends the LUMC Director of Clinical Engineering a description of the equipment and the user's manual. LUMC Clinical Engineering informs LUMC CR if inspection is needed.

C. **IT Requirements**

1. Equipment may connect to LUMC's Guest internet if needed.
2. If equipment requires connection to LUMC's secure internet, the equipment must be managed by LUMC. LUMC must have control of the installation of anti-virus, security patches, and other software required to protect the integrity of its network.
   a. LUMC CR will submit a ServiceNow ticket to IT to request a cost and effort estimate of managing the equipment.
   b. LUMC CR will provide the cost estimate to the Study Team for inclusion in the study budget.
   c. LUMC CR will facilitate communications between the Study Team and IT to ensure IT is able to manage the equipment as soon as possible after the equipment arrives at LUMC.
3. If equipment will store or transmit protected health information (PHI), LUMC CR will send a summary of the equipment and PHI to be contained in the equipment to the LUMC Chief Integrity Officer. LUMC CR will facilitate the Chief Integrity Officer's risk assessment and review as requested.

D. **Supply Chain Requirements**

1. If LUMC is purchasing the equipment, LUMC CR facilitates LUMC Supply Chain's review of the pricing and purchasing language in the purchase addendum.
2. All items to be controlled by LUMC are to be shipped to LUMC. All items shipped to LUMC are required to have a PO. This requirement will be communicated to the sponsor before study initiation.
3. LUMC CR facilitates creation of a Research Requisition for the equipment and supplies to be sent to LUMC and provides it to the Study Team.
4. The Study Team emails the completed Requisition to LUMC Supply Chain when an item is needed from the sponsor or vendor.
5. LUMC Supply Chain provides the PO to the Study Team.

a. If LUMC is ordering the item from the sponsor, LUMC Supply Chain forwards the PO to the sponsor via its normal order process.
b. If LUMC is not ordering the item directly from the sponsor, the Study Team provides the PO to the sponsor.

6. The Study Team facilitates scheduling the most appropriate time and place for item delivery with the supplier and LUMC CR, particularly for items requiring special storage conditions
7. When the item arrives at the LUMC receiving dock, the dock contacts LUMC CR for retrieval.

IV. REFERENCES

A. The Joint Commission Accreditation Manual Glossary, Hospital, version July 1, 2017
B. 21 CFR 812 FDA Investigational Devices
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=812
C. SOP PRO-001 Investigational Device Storage and Accountability
D. Policy CR-002 Institutional Approval of Research
E. 42 CFR 482.42 CMS Infection Control
https://www.gpo.gov/fdsys/pkg/CFR-2011-title42-vol5/pdf/CFR-2011-title42-vol5-sec482-42.pdf
F. 42 CFR 482.41(c)(2) CMS Physical Controls
https://www.gpo.gov/fdsys/pkg/CFR-2011-title42-vol5/pdf/CFR-2011-title42-vol5-sec482-41.pdf
G. The Joint Commission Accreditation Manual, Hospital, version July 1, 2017
Sections IC.02.02.01, EP.4 and EC.01.01.01
H. 77 Ill Admn Code 250.1290(e) Illinois Hospital Licensing Requirements, Safety
ftp://www.ilga.gov/jcar/admincode/077/077002500J12900R.html

V. ASSOCIATED DOCUMENTS AND FORMS

A. Research Requisition

VI. APPROVALS

LUMC EVP, Clinical Affairs (or designee) — Date: 4-12-18

LUC Senior Director, Clinical Research Office — Date: 4-16-18