LOYOLA UNIVERSITY CHICAGO

Equipment Provided to LUC
PRO-017

Effective date: 01 NOV 2019

I. SCOPE

Equipment and supplies provided to Loyola University Chicago (LUC) for use in a research study by a sponsor or vendor. This does not include equipment purchased by LUC.

II. Definitions

"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 assessing a new research study, the principal investigator and/or his/her designee ("Study Team") determines if equipment or supplies will be provided to LUC by the sponsor.
2. The Study Team determines if the equipment or supplies may be managed by LUC or have to be managed by another institution, such as Loyola University Medical Center (LUMC).
    a. As defined in SOP PRO-005 Management of Research Equipment in LUMC, 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
    b. If all criteria are met, the equipment may be managed by LUC. Examples of equipment managed by LUC are tablets that are dispensed to research participants for home use.
3. If the supplies or equipment will be managed by LUC, the Study Team is responsible for:
    a. 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.
    b. Annual tracking of the equipment.
    c. Proper dispensing/distribution to correct research participant (see attached log)

d. Ensuring items are disinfected according to the manufacturer's IFU before use by research participants.
e. Ensuring items are not expired before use with research participants
f. Confirming the sponsor will provide training on, customer support for, and maintenance of sponsor-loaned equipment and facilitates these activities with the sponsor.
g. Arranging the ordering, shipping, and storage of items.
h. Returning equipment and supplies as directed by the sponsor and the contract.
i. Notify manager if equipment is suspected to be missing, stolen or not returned.

4. If equipment will be used with a patient in LUMC facilities, the Study Team is required to contact LUMC Clinical Engineering to complete an Incoming Safety Inspection. Refer to SOP PRO-005 Management of Research Equipment in LUMC.
5. The individual(s) operating the equipment or supplies must notify the Risk Management and departmental manager immediately if the equipment or supplies are suspected of causing harm to a research participant, 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 LUC Risk Management. Notify sponsor and/or vendor immediately.

B. IT Requirements and Polices:
https://www.luc.edu/its/aboutits/itspoliciesguidelines/policy_access_use.shtml
https://www.luc.edu/its/aboutits/itspoliciesguidelines/networkfirewallpolicy/

IV. REFERENCES

SOP PRO-005 Management of Research Equipment in LUMC

V. APPROVALS

10/18/19

LUC Senior Director, Clinical Research Office (or designee) Date