I. SCOPE

This SOP describes the Loyola University Medical Center (LUMC) and Loyola University Chicago (LUC) responsibilities related to the management of investigational devices to be utilized in LUMC. Software investigational devices are outside the scope of this SOP.
This SOP is complementary to SOP Management of Research Equipment in LUMC.

For investigational devices to be controlled by LUMC, LUMC is responsible for receiving, storing, returning, and/or disposing of investigational devices according to the study contract, the device's Instruction for Use (IFU), and the IRB. LUC is responsible for adhering to all other aspects of the study protocol, including the Investigator's responsibilities as dictated by the sponsor and the FDA.

The Principal Investigator (PI) is responsible for confirming a patient's eligibility for the device.

II. DEFINITIONS

Investigational device is a device, including a transitional device that is the object of an investigation.

Investigational device exemption (IDE) refers to the regulations under 21 CFR 812. An approved IDE means that the IRB (and FDA for significant risk devices) has approved the sponsor's study application and all the requirements under 21 CFR 812 are met.

III. PROCEDURES

A. **Ordering, Receipt, and Storage of devices to be controlled by LUMC**

1. The device is to be ordered and received according to the research SOP PRO-005 Management of Research Equipment in LUMC.
2. If an investigational device is brought in on the day of use, and no storage is required, the PI or his/her designee ("Study Team") is responsible for maintaining the accountability log.
3. If the investigational device is delivered before the day of use, LUMC Clinical Research personnel (LUMC CR) is responsible for maintaining the accountability log. Upon receipt of the investigational device, LUMC Clinical Research personnel (LUMC CR) documents the items received, the quantity, date received, batch number/code mark, and name of person receiving device.
4. LUMC CR ensures:
   a. The information on the packing slip matches the study product received
   b. The physical product is in good condition
   c. The device is appropriately labeled by the sponsor with the following:
      - Name and place of business of the manufacturer, packer, or distributer
      - Quantity of the contents if appropriate
      - Statement: "CAUTION -- Investigational Device. Limited by Federal (or United States) Law to Investigational Use."
      - Description of all relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings, and precautions.
5. If there is evidence of breakage, compromised storage, or product tampering:
   a. LUMC CR notifies the Study Team immediately
   b. LUMC CR removes the device from service, labels it "Do not use", and informs LUMC Clinical Engineering.
   c. The Study Team notifies the supplier immediately for further instructions.

6. LUMC CR completes the IDE Hand Off Form.
7. LUMC CR brings the device(s) and the IDE Hand Off Form to the designated storage area. The designated storage area:
   a. Must meet the requirements specified in the product's Instructions for Use (IFU)
   b. Must meet the IRB-approved protocol for investigational devices
   c. Must be accessible to the PI and his/her designee(s) ("Study Team")
8. LUMC CR notifies the Study Team that the device arrived and where it is stored. If the device is to be used on the day it is received, LUMC CR may deliver the device directly to the Study Team.
9. If the device is stored in a clinical area, LUMC CR ensures the department manager is informed of the device arrival and the controls required for the device as dictated by the contract and the IFU.
10. The Study Team is responsible for retrieving the device from the storage area, signing the IDE Hand Off Form, and delivering the device to the PI or Sub-Investigator for patient use.

B. **Device Use and Accountability**
   1. The Study Team is responsible for:
      a. Ensuring the Study Team and LUMC clinical staff are appropriately trained in the use of the device(s) if required. This training is documented in the training log kept by the Study Team and the employee's Human Resources record of LUMC employees.
      b. Ensuring the participant's informed consent is obtained prior to the performance of study procedures and placement / use of the Investigational Device.
      c. Using/applying the Investigational Device only as described in the IRB approved protocol.
      d. Ensuring relevant information is documented on the case report form (date of insertion/use, make and serial number of device).
      e. If the device is controlled by LUMC:
         - Notifying LUMC CR when a device is to be used.
         - Notifying LUMC CR when a device needs to be returned to the sponsor.
   2. If the device is controlled by LUMC, LUMC CR is responsible for documenting the use and disposition of each product received by LUMC, and returning product to the sponsor as dictated by the contract. LUMC CR retains the shipping package receipt.
   3. The PI is responsible for maintaining or delegating maintenance of the Device Accountability Log as dictated by the study sponsor and 21 CFR 812. If the sponsor does not provide a tracking log, the "Investigational Tool – Device Accountability Log" is to be used.

IV. REFERENCES

A. CFR 21 Part 812
B. SOP PRO-005 Management of Research Equipment in LUMC

V. ASSOCIATED DOCUMENTS AND FORMS

A. Investigational Device Tracking Log
B. IDE Hand Off Form

VI. APPROVALS

Katherine van Meurs 12/18/2019
LUMC Manager Clinical Research Operations Date

12/20/19
LUC Senior Director, Clinical Research Office Date

Revision History

Effective Date	Summary of Changes
15/Feb/2017	Initial version
1/Jan/2020	Reformatted and rephrased for clarity; added IDE Hand Off Form

LOYOLA UNIVERSITY HEALTH SYSTEM

LOYOLA UNIVERSITY CHICAGO

IDE Hand Off Form

PI:	LU:
Study Short Title:	Device:

Device ID	Patient ID	Stored By	Stored Date	Retrieved By	Retrieved Date

Signature of Individual who stored the device

Signature of individual who retrieved the device