I. SCOPE

This SOP applies to all investigators who propose or are conducting a research study that involves a medical device as the object of investigation.
The Institutional Review Board (IRB) is the institutional authority on whether a device is exempt from Investigational Device Exemption (IDE) regulations or is non-significant risk.

II. DEFINITIONS

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

Investigation is a clinical investigation or research involving one or more subjects to determine the safety and/or effectiveness of a device

III. PROCEDURES

1. The IDE Checklist is to be completed by an investigator when he/she is developing a research protocol that investigates a medical device or intends to utilize a medical device outside of its FDA-approved or cleared indication during the conduct of the study.
2. If the investigator determines the device is IDE Exempt, he/she retains the completed checklist with the study records.
3. If the investigator determines the device is non-significant risk:
   a. The IDE Checklist should be submitted to the IRB. If the IRB disagrees with the investigator's determination of non-significant risk, they study will require an IDE from the FDA.
   b. The investigator is required to comply with the abbreviated IDE requirements (21 CFR 812.2(b)):
      (1) Labeling - The device must be labeled in accordance with the labeling provisions of the IDE regulations (§812.5) and must bear the statement "CAUTION - Investigational Device. Limited by Federal (or United States) law to investigational use."
      (2) IRB Approval – The sponsor must obtain and maintain IRB approval throughout the investigation as a nonsignificant risk device study
      (3) Informed Consent – The sponsor must assure that investigators obtain and document informed consent from each subject according to 21 CFR 50, Protection of Human Subjects, unless documentation is waived by an IRB in accordance with §56.109(c)
      (4) Monitoring - All investigations must be properly monitored to protect the human subjects and assure compliance with approved protocols (§812.46). Guidance on monitoring investigations can be found in Guideline for the Monitoring of Clinical Investigations
      (5) Records and Reports - Sponsors are required to maintain specific records and make certain reports as required by the IDE regulations
      (6) Investigator Records and Reports – The sponsor must assure that participating investigators maintain records and make reports as required (see Responsibilities of Investigators)
      (7) Prohibitions –Commercialization, promotion, test marketing, misrepresentation of an investigational device, and prolongation of the study are prohibited (§812.7)
4. If the investigator determines the device is significant risk, the study requires an IDE from the FDA.
5. An external sponsor may provide its own device risk assessment but the IRB retains the authority to require FDA review if they find the device to be significant risk.

IV. REFERENCES

A. 21 CFR 812

V. ASSOCIATED DOCUMENTS AND FORMS

A. IDE Checklist
B. IDE Decision Tree
C. IDE Where to start? Information sheet

VI. APPROVALS

LUMC EVP, Clinical Affairs (or designee) — Date: 8/29/18

LUC Senior Director, Clinical Research Office (or designee) — Date: 8/24/18