

LOUIS STOKES CLEVELAND VA MEDICAL CENTER  
Medical Research Service  
Standard Operating Policy and Procedure (SOP)

**Effective Date:** October 5, 2005  
**SOP Title:** Ordering, Receipt, Storage and Usage of Investigational Device(s) for Research Subjects  
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**Department:** Medical Research Service

  
Signature

10.6.05  
Date

**Approved By:**

Associate Chief of Staff or Committee Chairperson

  
Signature

10/6/05  
Date

Committee Chairperson/Administrator (if applicable)

Signature

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**Effective Date:** October 5, 2005

**SOP Title:** Ordering, Receipt, Storage, and Usage of Investigational Device(s) for Research Subjects.

**SOP Number:** HSP-013

**SOP Version:** .00

**1. PURPOSE:** To establish a procedure for Ordering, receipt, storage, and usage of Investigational Device(s) for Research subjects

**2. POLICY:** It may be necessary for the PI's and site coordinators to order surgical devices or supplies for research patients

**3. DEFINITIONS**

a. **Investigational Device:** A device, including a transitional device, that is the object of a clinical investigation or research study that involves one or more subjects to determine the safety or effectiveness of a device.

b. **Investigational Device Exemption:** An FDA-approved IDE application permits a device, which would otherwise be subject to marketing clearance, be shipped lawfully ) in accordance with 21 U.S.C. 360j(g) and 21 CFR Parts 812 and 813 ) for the purpose of conducting a clinical trial in order to collect safety and effectiveness data required to support a Premarket Approval (PMA) application or a pre-market Notification (510d) submission to the FDA.

c. **Emergency Use:** This situation may arise where there will be a need to use an investigational device in a manner inconsistent with the approved investigational plan or by a physician who is not part of the clinical study. Emergency use of an unapproved device may occur before an IDE is approved.

d. **Compassionate Use:** This allows access for patients who do not meet the requirements for inclusion in the clinical investigation but for whom the treating physician believes the device may provide a benefit in treating an/or diagnosing their disease or conditions. This provision is typically approved to treat a small group.

e. **Humanitarian Device Exemption:** A device that is intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 4,000 individuals in the United States per year. FDA developed this regulation to provide an incentive for the development of devices for use in the treatment or diagnosis of diseases affecting thee populations.

f. **Consignment:** with the provision that payment is expected only on completed sales and that unsold items may be returned to the seller (cosigner).

g. **Purchase Order:** A commercial document used to request someone to supply in return for payment and providing specifications and quantities.

**4. RESPONSIBILITIES:**

a. Principal Investigators have ultimate responsibility to order, securely store, and keep a record of all devices ordered and implanted into a human subject.

b. Surgical Supply Manager (SSM) officially orders and receives the device.

**5. PROCEDURE:**

a. Ordering procedure is discussed in a group meeting with the PI, site coordinator, device company, and the Surgical Supply Manager (SSM) currently Bill Precht at ext 5130/5131. Location of the SSM is on the second floor room #2589 just outside the SICU.

b. Forms provided by the device company are to be filled out by the PI for each individual research subject. This form is given to the SSM who generates a purchasing order.

c. The device is sent directly to the office of the SSM.

d. The SSM will contact the PI/site coordinator to confirm the device is present.

e. This device may be stored in the SSM office or with the PI/site coordinator until the time of surgery.

f. The SSM maintains an ordering record and the PI/site coordinator will keep a record of each device in the subject's research folder.

**6. REFERENCE:**

a. VHA Handbook 1200.5, IRB SOP Manual; 21 CFR Parts 50,56,803,812,and 814; FDA Information Sheets "Guidance for Institutional Review Boards and Clinical Investigators," 1998

b. Medical Center Policy 151-015 "Investigational Devices Used In Human Studies."

**7. RESCISSION:** October 1, 2008

**8. FOLLOW UP RESPONSIBILITY:** Research Compliance Officer