1 PURPOSE

1.1 This guidance establishes the process for Sharp HealthCare (SHC) investigators review, storage, dispensing, accountability, returns, and adverse event reporting of investigational devices for clinical trials at SHC.

1.2 The guidance begins when the SHC Institutional Review Board (IRB) reviews research involving medical devices.

1.3 The guidance ends when the investigational device research is terminated, suspended, discontinued, or completed.

2 REVISIONS FROM PREVIOUS VERSION

2.1 If applicable, previous versions available in Human Research Protection Program Change Log.

3 POLICY STATEMENT

3.1 Research involving investigational devices must be reviewed and approved by the SHC IRB before such research may begin.

3.1.1 Proposals that the IRB determines to represent significant risk device research cannot proceed without submission of an Investigational Device Exemption (IDE) application to the Food and Drug Administration (FDA) and subsequent receipt of confirmation of the FDA decision on the application.

3.2 The principal investigator and sub-investigators approved by the IRB to conduct the research shall be members of the attending medical staff. The principal investigators and sub-investigators have the authority to use investigational devices or procedures for IRB approved research.

3.3 A signed, SHC IRB-stamped Informed Consent Form (ICF),California Experimental Subject's Bill of Rights and PHI Authorization form must be obtained from the patient or his/her legal representative prior to the initiation of any clinical trial research activity, except in the case of emergency use.

3.3.1 Proposals that the IRB determines to represent significant risk device research cannot proceed without submission of an Investigational Device Exemption (IDE) application to the FDA and subsequent receipt of confirmation of the FDA decision on the application.

3.4 Investigators who serve as a sponsor/investigator for an IDE research project are to follow FDA regulations 21 CFR 812 Subpart C applicable to sponsor responsibilities.

3.5 SHC requires a monitoring process for the receipt, dispensing, and record keeping concerning investigational devices that are studied using an IDE granted by FDA. The monitoring process shall be performed by the sponsor of the study and by the principal investigator or designee see *WORKSHEET – Investigational Device Accountability Log (HRP-308).*

3.6 In emergency circumstances, approval for the emergency use of an investigational device shall be obtained from the IRB chair or designee in the absence of the chair.

4 RESPONSIBILITIES

4.1 IDE sponsor/investigator, principal investigator or designee and IRB specialists carry out these procedures.

5 PROCEDURE

5.1 Before the research may begin, the IRB committee members:

5.1.1 Review and approve research involving medical devices using *WORKSHEET: Devices (HRP-307)* for pre-review.

5.1.2 Determines at a convened IRB meeting whether the research represents non-significant risk (NSR) device research or significant risk (SR) device research.

5.1.3 Document the NSR determination in the minutes.

Proposals that are determined to represent significant risk device research cannot proceed without submission of an Investigational Device Exemption (IDE) application

to the FDA and subsequent receipt of confirmation of the FDA decision on the application.

5.2 Federal regulatory and sponsor compliance monitoring specialists perform site visits of an investigator holding an IDE to assess compliance with FDA sponsor requirements in 21 CFR 812 before initiation of the research, and recommend corrective actions where appropriate (conducting follow-up routine monitoring visit one year after the pre-enrollment visit and subsequent monitoring visits, if necessary).

5.3 The investigator ensures the investigational device is used only in accordance with the IRB-approved protocol, the signed agreement, the investigational plan and applicable FDA regulations: administer the investigational device only to participants under the investigator's direct personal supervision or under the supervision of a sub-investigator directly responsible to the investigator.

5.4 Upon receiving IDE approval letter, IDE investigator completes *WORKSHEET: IDE Clinical Study Information (HRP-309)* and provides to the Research Office for submission to the Revenue Cycle department for Charge Description Master (CDM) charge code placement and assurance of proper claim submission of an investigational device.

5.5 The investigator or designee maintains the following accurate, complete, and current records relating to the investigator's participation in an investigation: records of receipt, use or disposition of a device that relate to the type and quantity of the device, the dates of its receipt, and the batch number, serial number, lot number, reference number, model number, sponsor designated number or code mark (if applicable), the names of all persons who received, used, or disposed of each device, and why and how many units of the device have been returned to the sponsor, repaired, or otherwise disposed of. Use *WORKSHEET: Investigational Device Accountability Log (HRP-308)* or the sponsor provided form to track placement of the investigational device.

5.6 Store Investigational Devices used in the context of research in appropriate areas in a facility other than the pharmacy, under the direct supervision of the Principal Investigator and in accordance with the sponsor, if applicable.

5.6.1 Store under appropriate environmental control in limited access areas separate from routine device stock and lock in the secure location.

5.7 When an investigational device is transported from one research site to a different site or entity, the courier (e.g., courier company employee, SHC employee) ensures the device is accompanied by a *WORKSHEET: Investigational Device Transport Log (HRP-319)*.

5.7.1 The designee completes the information in the header and Investigational Device Dispensation section of the Transport Log. A copy of the partially completed Transport Log is kept at the original research site and held until the receiving site receives a copy of the completed Transport Log or the original form is filed in the Study Binder. The study coordinator keeps the original completed Transport Log at the receiving site. Courier staff or the study coordinator completes the Transport section of the Transport Log.

5.8 If an unanticipated adverse event is to occur associated with the investigational device, the investigator/sponsor holding the IDE is to directly report to the IRB and FDA in an expedited manner the following adverse event information:

5.8.1 Unanticipated adverse events investigated under a sponsor's monitoring requirements [21 CFR 812.46(b)], must be reported to FDA within 10 working days after the sponsor receives notice of the effect.

5.9 When the investigation is terminated, suspended, discontinued, or completed, the investigator returns any unused supplies of the investigational device to the study sponsor, or otherwise provide for disposition of the unused supplies as directed by the sponsor.

5.10 When investigational device (e.g. stents, leads) or medical equipment, to include loaners is to be shipped into Sharp HealthCare, these devices must be clean, in good repair and good working order, FDA or Certificate Application Process (CAP) approved, and have a valid "no-

charge" paperwork/authorizations to the Sharp Facility, the medical equipment or devices will be received into the site Supply Chain Services. *Use PROCESS MAP: Study Device Workflow (HRP-795) for guidance.*

5.10.1 For medical equipment, notification must be given two days in advance to site Supply Chain Services prior to equipment delivery.

5.10.2 The equipment must be checked and approved by a clinical engineer/Biomed prior to being delivered to the department if applicable.

5.10.3 Suppliers/Service representatives with medical equipment will present the equipment for testing in advance of the procedure or use in patient care areas, so clinical Engineering can perform the necessary electrical safety checks and/or functional tests on the equipment if applicable. Testing may be time consuming so arrangements should be made well in advance.

6 MATERIALS

6.1 WORKSHEET: Devices (HRP-307)
6.2 WORKSHEET: Investigational Device Accountability Log (HRP-308)
6.3 WORKSHEET: IDE Clinical Study Information (HRP-309)
6.4 WORKSHEET: Investigational Device Transport Log (HRP-319)
6.5 PROCESS MAP: Study Device Workflow (HRP-795)

7 REFERENCES

7.1 None

This document is available on IRBANA or by contacting research@sharp.com.