I. BACKGROUND

Investigational devices are carefully regulated and must be appropriately controlled to ensure they are not co-mingled with similar approved devices. The nature of devices varies and it is difficult to state a single storage mechanism for control of devices. Some devices must be maintained in sterile supply, autoclaved or processed before they may be used in research subjects, other devices must be custom ordered while others are provided in a variety of sizes to allow fitting. Moreover, other devices are large and/or may require installation in a stationary location. Regardless of the type of investigational device, it is important that Investigators adhere to the following policy and procedures for ensuring adequate control of investigational devices.

II. PURPOSE

To assure appropriate control and use of investigational devices by Investigators who are qualified and licensed care providers.

III. DEFINITION

Investigational device is any health care product that does not achieve its primary intended purposes by chemical action or by being metabolized and is not approved for marketing in the U.S. Medical devices include, among other things, surgical lasers, wheelchairs, sutures, pacemakers, vascular grafts, intraocular lenses, and orthopedic pins. Medical devices also include diagnostic aids such as reagents and test kits for in vitro diagnosis of disease and other medical conditions such as pregnancy.

IV. POLICY

A. Prior to administration of the investigational device, approval must be granted by the UCI Institutional Review Board (IRB) and other hospital and federal regulatory bodies (e.g., FDA) as appropriate.

B. Device Accountability Log: The Investigator must keep accurate, complete, and current records relating to their participation in a clinical investigation. A device accountability log must be maintained by the Investigator, documenting 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 or code mark; 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.

C. Delivery: Devices should be delivered to the Investigator after UCI IRB approval is obtained and all other School of Medicine and hospital approvals are secured.* If this is not feasible (e.g., device requires, installation, testing, calibration, etc.) the Investigator should contact the Office of Clinical Research Oversight to secure permission to bring the device to the campus or the hospital. **Note: It may be necessary to acquire a number of approvals prior to delivery and installation of the device.*

D. Management: The IRB approved protocol should describe how the device will be managed. This includes who will have access to the device and how the investigational device stock will not be used in place of approved devices for non-research subjects.

E. Storage: Devices must be stored in a separate, locked area, away from approved devices and labeled to reflect "Investigational Device—Research Use Only."

F. Use: Investigational devices may only be used by an IRB approved Investigator in accordance with an IRB approved protocol, and for subjects who have consented to participate in the approved research study.

G. Disposal: The Investigator (or Sponsor / Manufacturer) must provide direction for the disposition of unused, damaged or faulty devices and for the disposition of all stock and/or equipment at the termination of the research study. Devices cannot be maintained after the conclusion of the study, unless they have FDA marketing approval and the Investigator has secured hospital approval to maintain the device for clinical research.

V. PROCEDURES

RESPONSIBLE PERSON(S)/DEPT	**PROCEDURE**
Investigator or Authorized Co-Investigator	1. Checks medical chart to be sure a copy of the signed informed consent document and a copy of the IRB approved protocol narrative, with current approval date and required signatures**,** has been placed under the Medical-Legal section. 2. Reviews protocol and device usage information. 3. Demonstrates understanding of device use criteria and sources of information. 4. Delivers, manages, stores, uses and disposes of devices per hospital policy.

RELATED POLICIES AND PROCEDURES:
Informed Consent, Research Protocols

Author: Alisa Irwin
Director, Research Protections

Approvals:

UCI ORA:	April 26, 2006
UCI IRB:	April, 27, 2006
Policy Review Committee:	January 06, 2007
Performance Improvement Committee:	January 10, 2007
Med Exec Committee:	January 22, 2007
Governing Body:	January 22, 2007