

Subject:		Issued By:	
<b>INVESTIGATIONAL MEDICAL DEVICES</b>		ADMINISTRATION	
		Approved By: Kathleen R. Hurtado President & CEO	
Policy #:	Issue Date:	Revised Date:	Effective Date:
301	May 1, 2007		May 2, 2007

Reference: For additional information on FDA policies and procedures governing Investigational Medical Devices look here: <http://www.fda.gov/cdrh/ode/idepolicy.pdf>.

**PURPOSE**

To describe the appropriate procedures for ordering, handling, receipt, dispensing, storage and disposition of Investigational Medical Devices used in clinical trials being administered by HRA.

**POLICY**

1. **THIS POLICY WILL BE FORWARDED TO ALL PIS WORKING WITH INVESTIGATIONAL MEDICAL DEVICES:** In addition to making this policy available on the HRA website, HRA will also e-mail a copy of this policy to any Principal Investigator (PI) who will be working on an Investigational Medical Device study. Such distribution will occur only after the study's protocol has received final IRB approval and a copy of the study's fully-executed contract is on file at HRA's administrative offices;
2. **PROTOCOLS MUST BE IRB-APPROVED WITH A FULLY-EXECUTED CONTRACT:** As with all studies being administered by HRA, no patients may be contacted and/or recruited – and no Investigational Medical Devices may be ordered and/or received – until such time as a study's protocol receives final IRB approval and after a fully-executed contract is on file with HRA;
3. **PI'S ARE TOTALLY RESPONSIBLE FOR PROPER DEVICE STORAGE, HANDLING AND ACCOUNTABILITY:** The PI is completely responsible for the proper ordering, receipt, dispensing, handling, storage and eventual disposition of every Investigational Medical Device used in HRA clinical trials;
  - a. **ORDERING:** Ordering of Investigational Medical Devices must be done by the PI, or their designated Study Personnel, according to the terms of the fully-executed contract and only after the protocol has received final IRB approval;
  - b. **RECEIPT:** Investigational Medical Devices may only be received by a PI, or their Study Personnel, at their office of business. The delivery address must be on file with HRA as a valid business address for the PI in question. No devices may be received prior to final IRB approval and prior to HRA's receiving a fully-executed contract at its administrative offices;

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- c. **DISPENSING:** A single Investigational Medical Device may only be dispensed to a single patient unless otherwise specified in the study’s fully-executed contract and IRB-approved protocol. For accountability purposes, a record of such dispensing must be made in an Investigational Medical Device Dispensing Log, in accordance with the Sponsor’s protocol. Dispensing Logs must be made available to study monitors/auditors upon request;
  - d. **HANDLING:** PIs and their Study Personnel must handle investigational medical devices carefully and in accordance with a study’s IRB-approved protocol and fully-executed contract and/or additional guidelines provided by the study’s Sponsor. Particular attention should be paid to reducing any risk of “treatment-acquired” patient infections;
  - e. **STORAGE:** Investigational Medical Devices must be stored in a secure (i.e. locked) area, with limited access, that is temperature controlled and free of moisture. Investigational Medical Devices must be stored separate from any non-investigational medications or devices, and also separate from all commercial supplies. Each Investigational Medical Device being stored must be labeled properly; including the name of the PI, the study number and the IRB number. Additional storage requirements may be outlined in a study’s IRB-approved protocol and must be followed by the PI and their Study Personnel in detail;
  - f. **DISPOSITION:** Investigational Medical Devices must typically be returned to the study’s Sponsor upon conclusion of the study. Instructions for returning devices should be included in a study’s IRB-approved protocol and/or its fully-executed contract. **UNDER NO CIRCUMSTANCES** should any Investigational Medical Device be destroyed by a PI, or their Study Personnel, without obtaining advanced written permission from a study’s Sponsor;
4. **DEVICE DISPENSING LOGS – ONE DEVICE PER PATIENT:** Unless otherwise specified in a study’s final IRB-approved protocol and/or its fully-executed contract, single Investigational Medical Devices are to be used on only ONE patient. It is up to the PI to record which device went to which patient, on the appropriate date and time, on either a Dispensing Log provided by the study’s Sponsor, or on the Sample Investigational Medical Device Dispensing Log contained as the last page of this policy. Such records must be made available to study monitors/auditors upon request.

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**RESPONSIBILITY**

All PIs and their Study Personnel  
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