OFFICE FOR EDUCATION & QUALITY IN CLINICAL RESEARCH		
	CATEGORY	**Clinical Research: Project Activities**
	SUBJECT	**Investigational Device Accountability**
	SOP #	**4.5**
	EFFECTIVE DATE	**August 6, 2008**
	REVISION DATE	**January 3, 2018**

OBJECTIVE

Describe how to account for investigational devices during the span of time they are on-site. These procedures apply to all clinical research activities approved by the Office for Human Subjects Research conducted within the Hennepin County Medical Center campus.

APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312 Investigational New Drug Application
21 CFR 812 Investigational Device Exemptions

REFERENCES TO RELATED SOPs

SOP 2.1
SOP 2.2
SOP 2.11
SOP 2.12

ATTACHMENTS

Sample Investigational Device Accountability Form

1) Upon receipt of investigational study devices:
   a) Ensure that the information on the packing slip corresponds exactly with what has been shipped to the site, report any discrepancies, breakage, or evidence of tampering to the sponsor.
   b) Ensure that the blinds (if applicable) are enclosed or that access to unblinding is defined.
      i) Maintain an investigational device accountability form.
      ii) Maintain proper storage for the investigational device.
         (1) Establish and maintain access controls for essential and/or appropriate research personnel.
         (2) Store the investigational device in a secure, locked environment along with controlled access.
         (3) Ensure the investigational device is stored at the appropriate temperature, maintain a storage area temperature log if appropriate.

2) The PI must assure that an investigational device is used only with subjects under the PI's personal supervision or under the supervision of a sub-investigator.

3) Study personnel must collaborate with appropriate personal (i.e., operating room, Radiology, Clinic Manger) to discuss the protocol and develop procedures appropriate to the study protocol and area in which the device will be placed.
   a) Document on the investigational device accountability form each time the study device is dispensed/used.
   b) Document:
      i) Subject's study ID number
      ii) Date
      iii) Person dispensing the study device
   c) Notify the sponsor when additional study devices are needed.
   d) Unused devices, or any retrieved devices used or opened must be returned to the sponsor according to the study protocol.
   e) Ensure that a copy of all study device return receipts and dispensing documents are placed in the regulatory binder.

SAMPLE DEVICE ACCOUNTABILITY LOG

DEVICE RECEIPT				DEVICE USE					DEVICE RETURN					
Date Rec'd	Initials	Lot # Serial# or Model#		Date Used	Initials	Subject ID #	Comments		Returned	Date	Initials	Lot # Serial# or Model#	Reason	Comments