TITLE: INVESTIGATIONAL DEVICE ACCOUNTABILITY

1.0 OBJECTIVE:

1.1 This Standard Operating Procedure (SOP) describes the procedures and applies to all protocols that use an investigational device product at MCG, MCG HI, and the Charlie Norwood Veterans Affairs Medical Center regardless of the governing IRB.

1.2 This procedure is intended to meet the following regulations while recognizing that these regulations may override the procedure:

- Food and Drug Administration (FDA) Federal Regulations (21 CFR 50, 54, 56, 312, 314, 600, 601, 812 and 814)
- Department of Health and Human Services (DHHS) Regulations (45 CFR Subparts A, B, C, and D)
- International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines
- Medical College of Georgia (MCG), Medical College of Georgia Health, Inc. (MCGHI), and Medical College of Georgia Research Institute (MCGRI) guidelines.

2.0 RESPONSIBILITIES:

2.1 The Investigators conducting studies in which investigational devices will be used must follow FDA regulations for device storage, accountability, dispensing/administration and record-keeping.

2.2 Investigators will demonstrate understanding of the handling and control of investigational test articles by reviewing this policy and developing a written plan or procedure for ensuring these regulations are met. If the device is also considered a medication by the FDA, it must be handled by the MCG Health Pharmacy or the Charlie Norwood VAMC Pharmacy according to the MCG SOP Number 03 on Investigational Drug Handling.

3.0 RECEIPT AND INVENTORY OF STUDY DEVICES

This section applies to those study devices the investigator dispenses/administers to the study subject. The investigator (or designated research team member) is responsible for ensuring that the following sections are fully documented and complete.

3.1 Upon receipt (preferably within 2 working days, but definitely prior to dispensing) of the study device:

3.1.1 Conduct an inventory of the shipment to ensure that the information on the packing slip matches exactly with what has been sent to the site, to include the receipt date, lot numbers, device type, batch number, code mark, and quantity.

3.1.2 Identify and document the name of the person who received the shipment of devices as well as their role on the protocol.

3.1.3 Discrepancies must be promptly (usually within 2-3 working days) reported to the Sponsor/Supplier of the device.

3.1.4 Documentation of this shipment inventory including the above information
must be maintained by the principal investigator or designee.

4.0 DOCUMENTATION FOR THE REGULATORY BINDER
4.1 Copies of the following documents must be retained:
   • The shipping inventory, packing slips and document inventory in the regulatory binder.
   • Accountability log (most Sponsors will issue/supply a device accountability log). See also Sample Device Accountability Log.

5.0 LABELLING OF STUDY DEVICES
Study devices from Sponsor companies are pre-labeled.

5.1 Do not re-label, deface, or change in any way without prior written permission of the Sponsor.
5.2 It is highly recommended that an additional label may be placed on the study device or packaging, if space and the design of the device permits, to include the study staff contact name/number, but ONLY if the Sponsor agrees in writing prior to doing so.

5.3 Principal Investigator Responsibilities
   The Principal Investigator must be aware of applicable FDA regulations and at a minimum, include the following on the label (if allowed by the sponsor) or on the packaging:
   • Name of device
   • Model number
   • Serial number
   • Manufacturer name
   • Study staff contact name/number

5.3.1 The FDA may designate the study device as “Investigational” and if so there must be a label with all of the following information:
   • Name and place of business of the manufacturer, packer, or distributor.
   • Quantity of contents if appropriate
   • And the following statement: "CAUTION-Investigational device. Limited by Federal (or United States) law to investigational use."
   • All relevant contraindications, hazards, side effects, interfering substances or devices, warnings, and precautions.

6.0 STORAGE OF STUDY DEVICES (INCLUDING DEVICES THAT RECORD DATA FROM AUTOMATED INSTRUMENTS)
6.1 Principal Investigator Responsibilities
   The Principal Investigator is responsible for establishing and maintaining appropriate access controls for essential and appropriate research personnel. The access controls must include, at a minimum, the following areas:
   • Develop procedures for verifying physical access
   • Store the study device in a secure environment to include locks on doors and controlled access.
   • Establish equipment control both into and out of the research site.
   • Develop Security Incident Procedures to report any privacy breaches
   • Assess any privacy risks anticipated and develop methods to avoid those risks
   • Develop data backup, storage, and emergency mode procedures, if applicable.
   • Ensure the study device is stored at the appropriate temperature, and maintain a storage area temperature log, if appropriate.
7.0 STUDY DEVICE DISPENSING

7.1 The Principal Investigator shall permit an investigational device to be used only with subjects under their personal supervision or under the supervision of a properly trained sub-investigator responsible to the Principal Investigator.

7.2 The Principal Investigator shall not permit an investigational device to be used with subjects who are not under their personal supervision or not under the supervision of a properly trained sub-investigator responsible to the principal investigator.

8.0 DOCUMENTATION OF STUDY DEVICE USE

8.1 The investigator must create and maintain an access log to document the following:
   • Each time the study device is dispensed/used
   • Where it is dispensed/used to
   • Whom it is dispensed/used
   • And the date and signature or initials of the person dispensing/using the study device (plus any other information dictated by the study protocol).

9.0 DOCUMENTATION OF RETURN/DESTRUCTION OF THE STUDY DEVICE (AS APPLICABLE TO THE SPECIFIC DEVICE)

9.1 The Principal Investigator must verify:
   • All documentation regarding receipt, storage, dispensing, return of used containers, and accountability is complete and accurate.
   • An explanation of why and how many device units have been returned to the sponsor, repaired, or otherwise disposed of must be noted. When a device is disposed of, the identification of the person who did so must also be noted.
   • Devices obtained from a Sponsor for the specific purpose of a research study must be returned to Sponsor. Only with the written authorization (i.e. in the protocol or other written correspondence) of the Sponsor (and in compliance with Federal regulations and Institutional policies) may the investigator discard the device on site, or retain the device.
   • Pursuant to 21 CFR 812.110, upon completion or termination of a clinical investigation or the investigator's part of an investigation, or at the sponsor's request, an investigator shall return to the sponsor any remaining supply of the device or otherwise dispose of the device as the sponsor directs.
   • Unused study devices that include individually identifiable health information must not be transferred to other investigators without IRB approval or an authorization from the study subject.
   • Unused study devices without individually identifiable health information must not be transferred to other investigators, used for animal research, or dispensed to non-study patients unless written consent is obtained from the Sponsor/Provider of the device.

10.0 RESEARCH ON FDA APPROVED DEVICES FOR FDA APPROVED INDICATIONS

10.1 This type of research requires documentation of receipt, storage, dispensing and return of the device as above. The FDA approved label is adequate, although including information specific to the study is recommended.

11.0 RESEARCH ON STUDY DEVICES THAT EMIT RADIATION
11.1 Radiation emitting devices have similar requirements as above. However, there may be specific requirements based on the device and the study design and thus each study must be discussed with the applicable institutional Radiation Safety Officer. Documentation of Radiation Safety clearance is required prior to use of the device.

12.0 REGULATIONS AND GUIDELINES
21 CRF 812 Investigational Device Exemptions
21 CFR 814 Pre-Market Approval of Medical Devices

12.0 INSTITUTIONAL REVIEW BOARD CONFIRMATION OF INVESTIGATORS
COMPLIANCE AND TRAINING
12.1 Human Assurance Confirmation (HAC)
12.1.1 At the time of initial protocol review and approval, the investigator must document procedures for ensuring appropriate device storage, security, accountability records and appropriate use.
12.1.2 Compliance with the process is monitored at the time of continuing review as the investigator reports to the HAC the status of the study. The Research Self-Assessment Checklist is also completed at the time of continuing review and is provided to the HAC.

12.2 Chesapeake Research Review, Incorporated (CRRI)
12.2.1 Refer to the CRRI website for their specific requirements regarding compliance

12.3 If an investigator plans to use an investigational device, the OHRP will provide ad hoc training on this information related to investigator responsibilities for storage and handling.

13.0 INCLUSION OF THE TYPES OF STUDIES IN THE OHRP AUDITING AND COMPLIANCE PROGRAM
13.1 These studies are also subject to audit by the OHRP Auditing and Compliance program.
13.2 If selected for audit, the logs and destruction records must be available for review.

14.0 DEFINITIONS
Device means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component part, or accessory, which is (1) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Custom device means a device that: (1) Necessarily deviates from devices generally available or from an applicable performance standard or premarket approval requirement in order to comply with the order or an individual physician or dentist; (2) Is not generally available to, or generally used by, other physicians or dentists; (3) Is not generally available in finished form for purchase or for dispensing upon prescription; (4) Is not offered for commercial distribution
through labeling or advertising; and (5) Is intended for use by an individual patient named in the order of a physician or dentist, and is to be made in a specific form for that patient, or is intended to meet the special needs of the physician or dentist in the course of professional practice. 

**Investigational device** means a device, including a transitional device, which is the object of an investigation. 

**Transitional device** means a device subject to section 520(l) of the act, that is, a device that FDA considered to be a new drug or an antibiotic drug before May 28, 1976.

**Sponsor** means a person who initiates, but who does not actually conduct, the investigation, that is, the investigational device is administered, dispensed, or used under the immediate direction of another individual. A person other than an individual that uses one or more of its employees to conduct an investigation that it has initiated is a sponsor, not a sponsor-investigator, and the employees are investigators. 

**Sponsor-investigator** means an individual who both initiates and actually conducts, alone or with others, an investigation, that is, under whose immediate direction the investigational device is administered, dispensed, or used. The term does not include any person other than an individual. The obligations of a sponsor-investigator under this part [21 CFR 812 Subpart C] include those of an investigator and those of a sponsor.

15.0 APPENDIX

Sample Device Receipt Log
Sample Device Accountability Log