

MANAGEMENT OF INVESTIGATIONAL DEVICES PROCEDURES

OBJECTIVE:

To outline procedures for management and inventory control of Investigational Devices (IDs) used in approved research protocols at the Atlanta VA Medical Center

IRB review and approval and investigator conduct of all investigational device studies must be in accordance with all applicable VA and other requirements. If the research involves FDA-regulated devices, both VA and FDA requirements apply. FDA regulations supersede VA requirements for human subjects research under FDA jurisdiction unless VA requirements are more restrictive than applicable FDA regulations.

PROCEDURES:

- a) Devices will be administered only to subjects who have agreed to participate in the study and signed an Informed Consent Form
- b) Record receipt of the device on the Investigational Device Log throughout the study to maintain an accurate inventory and utilization record.
- c) The PI or study staff should ensure that the ID package has a label with name/place of manufacturer, distributor and quantity of contents. The label must describe all relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings and precautions.
- d) Store IDs in a secure, locked area specifically designated for research supplies. Do not store IDs with approved devices used in standard medical care.
- f) The ID must be administered only to participants under the PI's direct personal supervision or under the supervision of a co-investigator who is directly responsible to the PI.
- g) The ID Log should include:
 - I. Type and quantity of the device, the dates of receipt, and the batch number or code mark
 - II. The names of all persons who received, used, or disposed of each device
 - III. Number of units returned to the sponsor, repaired, or otherwise disposed of along with an explanation for each entry.
- h) Upon completion or termination of the study, the Investigator shall return any remaining supplies to the sponsor or otherwise dispose of the IDs as instructed by the sponsor.
- i) The Research Compliance Officer will conduct an annual inventory audit of all device logs and report these findings to the R&D Committee.