Device Accountability in Clinical Research

Managing research device inventory & tracking

Objectives

♦ Define device accountability
♦ Review the two main categories of research devices
♦ Describe the Penn Medicine requirements for proper device accountability for clinical research studies
♦ Describe support services for research device accountability
Device Accountability

- Accountability of research devices involves a standard, verifiable process of managing the disposition of the device, including:
  - Receipt by the investigator/investigator’s institution
  - Assessment of condition of the device (e.g. damaged, functional vs non-functional, etc.)
  - Assignment of devices to research subjects
  - Tracking of devices
  - Management and disposition of damaged or unused devices (e.g. destruction or return to the manufacturer or research sponsor)

- Device accountability is a regulatory requirement of all clinical research studies involving the use of a research device.

Categories of Devices

- A Significant Risk Device is an investigational device that:
  - Is intended as an implant
  - Is for use in supporting or sustaining human life
  - Is of substantial importance in diagnosing, curing, mitigating, or treating a disease or otherwise preventing impairment of human health
  - And presents a potential for serious risk to the health, safety, or welfare of a subject
  - Or otherwise presents a potential for serious risk to the health, safety, or welfare of a subject

- At Penn, the IRB makes the final determination if a research device is a Significant Risk Device or a Non-Significant Risk Device.
Implantable Research Devices

♦ The Operating Room’s Peri-operative Services Committee (POSC):
  • Clinical research studies involving implantable devices must be submitted to the POSC for review & approval

♦ Review involves assessment of the protocol and clinical trials agreement for:
  • Cost
  • Ordering
  • Shipping
  • Payment
  • Returns

♦ Research devices are not permitted in the operating room without prior the POSC’s approval

OR Device Accountability Processes

♦ Ordering of devices
  • Devices are ordered from the sponsor through a Purchase Order request form
  • The study team completes the PO request form
  • The OR Materials Office processes the form:
    – Supplies a PO number
    – Submits the PO request form to the Sponsor
  • Devices are shipped directly to the OR for:
    – Inspection for damage
    – Verification against purchase order
    – Storage
OR Device Accountability Processes

♦ Receipt, inspection, & reordering of devices
  • Devices are shipped as stock consignment or on a per-patient basis
  • Once the device is received, the OR office notifies the study clinical research coordinator (CRC)
  • OR personnel and the CRC inspect & verify the shipment contents together
  • Confirmation of shipment and contents is documented
  • Damaged or discrepant items are noted & logged
    – The manufacturer and/or sponsor are notified
    – Damaged or discrepant items are returned to the sponsor or manufacturer
    – Return of such items is noted & logged
    – Replacement of damaged or discrepant devices is coordinated by the OR Materials Office and the study team consistent with the ordering process previously described

OR Device Accountability Processes

♦ Storage of devices
  • Research devices are stored separately from non-research devices in two main areas:
    – Radiofrequency cabinet
      – access requires electronic ID card to unlock cabinet
      – A device ID tag permits the system to track devices removed or returned
      – Tracking includes date & time stamp and identity of person removing/returning device
    – Stent closet - used primarily for storage of research stent devices
      – Locked access closet
      – Users log devices as removed or returned
  • Both research device storage areas are located within the OR
  • OR access is restricted to OR staff and OR-approved study staff as appropriate
OR Device Accountability Processes

♦ Inventory audit
  • The OR Materials Office and research team coordinate ordering replacement or additional devices
  • Periodic audits of on-hand inventory are conducted
  • Audit findings are cross reference with the OR HMS patient record system, a patient-specific system for documenting & tracking implanted devices

OR Device Accountability Processes

♦ Tracking implanted devices
  • Devices brought into an OR suite for patient implantation are logged into the HMS patient record system
    – Date & time device implanted and associated surgical staff
    – Specific patient
    – Catalog number
    – Device number
  • Disposition of such devices are noted in the HMS system (e.g. implanted, not-implanted, etc.)
  • Tracking of such devices follows the usual OR standard for tracking of non-research implantable devices.
OR Device Accountability Processes

♦ Record keeping
  • Working in collaboration with the study team, the OR maintains study-specific master files of device accountability records:
    – Shipping records
    – Order forms
    – Packing slips
    – Inventory audit findings
    – Return documentation
    – Device implantation tracking records
  • At the end of the study, OR study-specific master files are released to the study team

Non-Significant Risk Devices

♦ Study teams manage device accountability for non-significant risk devices

♦ The Investigational Drug Service Unit (IDS) now offers support in managing non-significant risk device accountability
IDS Device Accountability Processes

- Research studies using non-significant risk devices are submitted to the IDS for review
- Similar to the OR process, review involves assessment of the protocol and clinical trials agreement for:
  - Cost
  - Ordering
  - Shipping
  - Payment
  - Returns
- For studies determined to be best managed by the IDS service:
  - A service contract is prepared by the IDS
  - The contract is signed by the departmental business administrator prior to study start

IDS Device Accountability Processes

- **Ordering of devices**
  - Devices are ordered from the sponsor through the appropriate request form in collaboration with the research team
  - The the IDS processes the form
  - Devices are shipped directly to the IDS
  - Devices are received by the IDS for
    - *Inspection for damage*
    - *Verification against purchase order*
    - *logging into the IDS electronic inventory management system*
    - *Storage*
IDS Device Accountability Processes

♦ Receipt, inspection, & reordering of devices
  • Devices are shipped as stock consignment or on a per-patient basis
  • Confirmation of shipment and contents is documented in the IDS tracking system
  • Damaged or discrepant items are noted & logged
    – The manufacturer and/or sponsor are notified
    – Damaged or discrepant items are returned to the sponsor or manufacturer
    – Return of such items is noted & logged
    – Replacement of damaged or discrepant devices is coordinated by the IDS and the study team consistent with the ordering process previously described

IDS Device Accountability Processes

♦ Storage & access
  • The IDS facility maintains a controlled access and temperature storage area
  • The storage area is equipped with multiple security cameras
  • Devices may only be removed from inventory by a member of the IDS staff
IDS Device Accountability Processes

♦ Inventory audit
  • The electronic inventory indicates exactly what is on hand at all times
  • Par levels and reorder levels are assigned based on the needs of the particular trial.
  • Reorder reports are generated automatically from the system
  • IDS staffs periodically audit on-hand inventory as a quality-control assessment of the electronic system

IDS Device Accountability Processes

♦ Disposition of devices
  • A bar code system is used to track device location and disposition
  • Devices requiring certification by the hospital’s Biomedical Engineering Dept (e.g. infusion pumps):
    – *IDS makes arrangements for certification after receipt of device*
  • Devices are dispensed by the IDS to the appropriate study team member
    – *Every transaction is coded in the electronic system with a timestamp and the name(s) of the IDS staff member(s) involved in the transaction*
IDS Device Accountability Processes

♦ Record keeping
  • Working in collaboration with the study team, the IDS maintains study-specific master files of device accountability records:
    – Shipping records
    – Order forms
    – Packing slips
    – Inventory audit findings
    – Return documentation
    – Device implantation tracking records
  • Copies of the master file can be requested by the study team

Summary

♦ Research device accountability is a regulatory requirement
♦ Implantable significant risk device accountability is managed by the OR Materials office
♦ Typically investigative teams manage device accountability for non-significant risk devices
♦ The Investigational Drug Services unit provides device accountability services for non-significant risk devices