

<p><b>C</b>enter for <b>H</b>uman <b>P</b>henomic <b>S</b>cience</p>	<p>University of Pennsylvania Health System</p>	<p><b>CHPS</b> <b>SOP 18</b></p>
<p><b>Standard</b> <b>Operating</b> <b>Procedure</b></p>	<p><b>Research Equipment</b></p>	

**PURPOSE:**

To provide guidelines for safe and effective use of research equipment at the Center for Human Phenomic Science (CHPS). Research equipment refers to equipment that is utilized to conduct research and is not otherwise used within the University of Pennsylvania Health System (UPHS). This equipment may be supplied by the sponsor (“study-provided research equipment”) or owned by CHPS.

**SCOPE:**

CHPS staff and Clinical Study Teams (CSTs)

**RESOURCES:**

Penn Medicine/HUP Medical Equipment Management Plan 2023

**PROCEDURE:**

**1) General Principles**

- a) On the CHPS Intake Application, it must be communicated if study-provided research equipment will be used. Contact CHPS Nursing Leadership at the time of application to begin discussion of study-provided research equipment.
- b) The Principal Investigator (PI) is accountable for the oversight of this SOP with respect to the CST’s responsibilities.
- c) All research equipment, whether provided by the sponsor or owned by CHPS, whether operated by CHPS or the study team, must be tagged by Clinical Engineering with the following stickers:
  - i) Asset Number
    - (1) This allows Clinical Engineering to maintain the equipment in the hospital inventory.
  - ii) Non-UPHS Owned Equipment Electrical/Performance Check
    - (1) This ensures the equipment is safe to operate.
- d) CHPS is not responsible for study-provided research equipment left on the CHPS unit.

**2) Study-Provided Research Equipment operated by CHPS Staff:**

- a) If a protocol requests the use of study-provided research equipment that will be operated by CHPS staff, the CST must confirm with the sponsor that it is not possible to use equipment already approved at UPHS. CHPS Leadership must be included in these correspondences with the sponsor.
- b) If it is not possible to utilize equipment already approved at UPHS, the CHPS Nurse Manager will reach out to the Environment of Care (EOC) Committee to review the proposed research equipment (contact Frank.Connelly@pennmedicine.upenn.edu).
  - i) If accepted by the EOC Committee, normal procedures for tagging equipment and maintaining equipment will be followed by Clinical Engineering.
  - ii) If not accepted by the EOC Committee, Clinical Engineering will tag the equipment as outlined in section (1)(a).
- c) The following are all CST Responsibilities:**
  - i) Education
    - (1) Meet with CHPS Nursing Leadership to instruct them on use of the equipment early on. The study will not receive CHPS approval unless this education is completed.
    - (2) After the study has received CHPS approval, the CST must schedule an Equipment Education In-service to provide education about the proper use of the equipment to the rest of the CHPS staff.
      - (a) This instruction could be done by the CST or by the vendor.
      - (b) This is separate from the in-service that is required for protocol and nursing worksheet review.
    - (3) Notify and provide CHPS staff with new and ongoing education and training related to the equipment.
  - ii) CHPS Nursing Worksheets
    - (1) Incorporate a user-friendly instruction manual or guide to the equipment into the CHPS Nursing Worksheets.
    - (2) Provide contact information of persons available 24/7 to troubleshoot the equipment if it malfunctions on the CHPS Nursing Worksheets.
  - iii) Maintenance, Calibration, and Repair of Equipment
    - (1) Oversee the maintenance, calibration, and timely repair of the equipment.
    - (2) Maintain logs with this information.
    - (3) Provide the plan for inspection and maintenance to CHPS Nursing Leadership
    - (4) Send updated maintenance reviews and repair reports to CHPS Nursing Leadership.
    - (5) Provide back-up equipment prior to study start so that it is available in the event the equipment malfunctions.
  - iv) Study-Provided Infusion Pumps:
    - (1) Contact IDS about the study-provided infusion equipment and supplies (tubing, syringes, cannulas, etc.).

(2) Invite IDS to the Site Initiation Visit. A determination will be made regarding whether the CST or IDS will store the supplies.

**3) Study-Provided Research Equipment not operated by CHPS Staff:**

- a) Study-provided research equipment not utilized by CHPS staff refers to equipment that is owned and operated by Perelman School of Medicine staff or vendors associated with the study team.
- b) CHPS staff are not trained on this equipment because it is exclusively operated by the CST.
- c) Preventative maintenance, calibration, and cleaning logs are maintained by the CST and are available upon request.

**4) CHPS-Owned Research Equipment**

- a) CHPS will ensure proper training is conducted prior to use of equipment.
- b) CHPS will perform preventative maintenance on the equipment in accordance with the user manual and/or vendor training.

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