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| Center for Human Phenomic Science | University of Pennsylvania Health System | CHPS SOP 18 |
| Standard Operating Procedure | Study-Provided Equipment | Page 1 of 2 |

PURPOSE: To provide guidelines for safe and effective use of non-standard, study-provided equipment that is not used by the University of Pennsylvania Health System (UPHS) and not overseen by the system’s Environment of Care (EOC) Committee and Clinical Engineering (CE) Department.

SCOPE: CHPS staff and Clinical Study Teams (CSTs)

RESOURCES:

1. Penn Medicine/HUP 2019 Medical Equipment Management Plan

PROCEDURE:

1. On the application to use the CHPS, it must be communicated that study-provided equipment will be used. Contact CHPS Nursing Leadership at the time of application to begin discussion of study-provided equipment.
2. If a protocol requests the use of study-supplied equipment, the CST must confirm with the sponsor that it is not possible to use equipment already used at UPHS; CHPS Leadership must be included in these correspondences with the sponsor.
3. The use of study-provided, non-UPHS approved, equipment will be submitted by CHPS Nurse Manager to the Environment of Care (EOC) Committee (contact Frank.Connelly@pennmedicine.upenn.edu). If accepted by the EOC this SOP does not apply. This SOP addresses equipment not approved by the EOC and so, not maintained by CE.
4. Prior to in-servicing the CHPS nursing staff on equipment use, the CST will meet with CHPS Nursing Leadership to instruct them on its use. After the protocol has been approved by the IRB and CHPS Administration, CHPS Nursing Leadership will notify the CST when the device is approved for use on CHPS and the Equipment Education in-servicing can be initiated by the CST.
5. The CST is responsible for contacting IDS about the study-supplied infusion equipment and supplies (tubing, syringes, cannulas, etc) and inviting them to the Site Initiation Visit. A determination will be made regarding whether the study team or IDS will store the supplies.
6. If a study requires study-provided equipment, the CST is responsible for providing adequate education about the proper use of the equipment at an Equipment Education in-service for the CHPS staff. This instruction could be done by the study team or by the vendor. There will be a separate required in-service for protocol review and information on the nursing worksheets.

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7. A licensed RN/provider is responsible to program the pump prior to administration of medication.
8. The CST is responsible for providing a User-Friendly Instruction Manual/Guide for the CHPS nurses. This instruction guide is to be part of the nursing worksheet when infusions are given.
9. The CST is responsible for providing CHPS staff with the names and contact numbers of persons available 24/7 to troubleshoot equipment if it malfunctions.
10. The CHPS NP will email the CHPS nurses not present at the study's Equipment Education in-service attaching material distributed at the in-service.
11. The CST is responsible for the maintenance, calibration, and timely repair of the equipment and maintaining a log with this information.
12. The CST will provide the plan for inspection and maintenance of the device and send updated maintenance reviews and repair reports to CHPS Nursing Leadership.
13. The CST is responsible for providing back-up equipment in the event the equipment malfunctions.
14. The CST is responsible for notifying CHPS staff of any new and ongoing education and training related to the equipment.
15. The Principle Investigator is accountable for the oversight of this SOP in respect to the CST's responsibilities.
16. CHPS is not responsible for study-provided equipment left on the CHPS unit.

Addendum: Utilizing study-provided EKG machines is out of scope for this SOP. Study-provided EKG machines are commonly used by the CHPS staff, provided that they have received training by the CST on the proper operation of the equipment. The CST is responsible for maintaining training logs or study-provided EKG machines. CHPS is not responsible for study-provided EKG machines left on the CHPS unit.

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