Center for Human Phenomic Science	University of Pennsylvania Health System	CHPS SOP 31
Standard of Operating Procedure	Investigational Immune Effector Cell Therapy Administration	Page 1 of 3

PURPOSE: To enumerate the steps required for administration of investigational immune effector cell therapy (IECT) in the absence of specific instruction from the research protocol.

SCOPE: The Center for Human Phenomic Science (CHPS) nursing staff.

DEFINITION: Per the Foundation for the Accreditation of Cellular Therapy (FACT) Standards for Immune Effector Cells First Edition 1.1, an immune effector cell is "a cell that has differentiated into a form capable of modulating or effecting a specific immune response" (2018). This includes CAR T-cells, CAR macrophages, and various other novel immunotherapies.

PROCEDURE:

1. Place an 18- or 20- gauge peripheral intravenous (IV) catheter in a competent vein.
2. Pre-medicate with 650mg acetaminophen PO and 25mg diphenhydramine PO as ordered at least 30 minutes prior to administration of IECT product.
3. Perform dual nursing check with study team by comparing frozen IECT product labels against patient wristband and product requisition forms. The clinical research nurse (CRN) from the study team should be the second nurse for the dual nursing check.
4. A free-flowing macro-drip gravity line is established with a Y-spike adapter. A 500mL bag of 0.9% normal saline should be used to prime the line. Close the pinch clamp on the IECT line after priming is completed while leaving the pinch clamp on the saline line open (Figure 1 and 2).
5. Connect the tubing set-up to the inserted peripheral IV catheter. Patency of the line is ensured by fully opening the roller clamp and assessing for continuous flow of saline through the chamber. The flow rate can thereafter be decreased by partially closing the roller clamp. It should remain partially open until just before the IECT product is spiked (Step 9).
6. Obtain vital signs immediately prior to IECT product thaw.

7. Scan the participant wristband and perform Bar Code Medication Administration if IECT product is ordered in the electronic medical record.

8. IECT product is thawed in a 37 °C water bath by a trained study team member or a technician from the originating lab. Once the product is fully thawed, it is handed to the administering CHPS nurse.

9. Administer the IECT product:
    a. Stop the flow of saline by closing the pinch clamp leading to the saline bag as well as the roller clamp on the tubing.
    b. Spike the IECT product bag.
    c. Open the pinch clamp leading to the IECT product bag.
    d. Squeeze the drip chamber to pull the IECT product into the chamber.
    e. Open the roller clamp fully on the tubing: this is considered start of infusion. The IECT product is administered wide open to gravity.

10. Complete back-washing procedure twice to ensure complete delivery of the IECT product. Back-washing procedure is as follows:
    a. Once the IECT product bag is empty, lower the IECT product bag below the saline bag.
    b. Open the pinch clamp leading to the saline bag to allow the IECT product bag to fill with saline.
    c. Close the pinch clamp leading to the saline bag.
    d. Gently invert the IECT product bag back and forth to “wash” the cells.
    e. Return the IECT product bag to the IV pole and allow product to infuse wide open to gravity until empty.
    f. Repeat this process once.

11. Infusion is complete once the IECT product bag is empty after the second back-washing procedure.

12. Flush product with at least 30mL normal saline with the roller clamp wide open.

13. Obtain a set of post-administration vital signs.

14. Disconnect tubing from the peripheral IV catheter.

15. Discard entire administration set in a red biohazard waste receptacle.

16. If at any point during the administration of IECT product the participant experiences an infusion-related reaction, stop the administration immediately and consult with the covering provider.

17. Obtain vital signs every 15 minutes for an hour, then every hour for three hours.

18. Verify with clinical research study team that it is acceptable to discharge participant from unit after observation is completed.

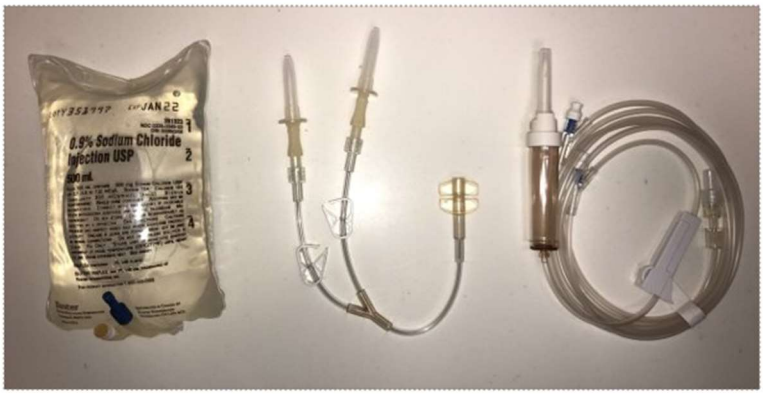

Figure 1. IECT product tubing supplies (own photo).

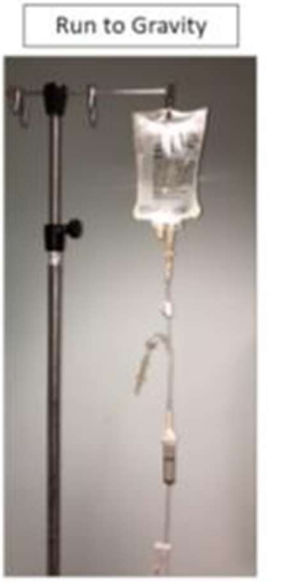

Figure 2. IECT product administration set up (own photo).

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