

## Virtual Facility Tour Requirements

### Clinical Facility Tour

1. Clinical Facility Space
  - a. Adequate space, size, and design of inpatient, outpatient, ambulatory, marrow harvest space
    - i. Inpatient Unit
    - ii. Inpatient room / anteroom
    - iii. Outpatient Area:
      - Waiting Room
      - Exam / interview rooms
      - Infusion Rooms
    - iv. ICU – location and access
    - v. Emergency Room (or equivalent)
  - b. Designated areas adequate to protect patient from transmission of infectious agents
    - i. Allows patient isolation
    - ii. Permits confidential evaluation
    - iii. Adequate space and design for infusions (IV fluids, medication, blood products)
  - c. Facility cleaning and sanitation, maintain order/space for operations
  - d. Adequate equipment and materials for procedures performed
    - i. IV infusion pumps,
    - ii. Adequate emergency equipment and supplies (e.g., code cart)
  - e. Operations to minimize risks to health and safety of employees, recipients, donors, visitors, and volunteers (e.g., signage regarding visitors). Also follow up at interview with staff.
  - f. Environmental controls – air handling, HEPA filters (if used), negative pressure, temperature control (note any monitors, gauges, etc.). Follow up with record review
2. Supply Storage
  - a. Inpatient, outpatient, ambulatory spaces, treatment rooms, pharmacy, general storage on the unit

- b. Adequate workspace to prevent mix-ups, deterioration, contamination, cross-contamination, and improper release of products and supplies
    - c. Controlled and monitored temperature and humidity of storage areas, noting individual storage requirements for specific supplies, reagents, drugs
    - d. Quarantine storage
3. Nursing: SOPs present – suggest having a nurse walk through SOP access, including back up process in case the primary system is unavailable.
4. Pharmacy
  - a. Providing 24-hour service, and prompt access to medications to treat complications of HCT and IED, including CRS – CONFIRM Tocilizumab present
  - b. Pharmacy delivery system
  - c. Investigational pharmacy
  - d. SOPs and treatment protocols available – demonstrate availability or access
5. PPE: gloves and protective equipment, include all personal protective equipment.
  - a. Show proximity of PPE to area of use.
  - b. Show where extra is stored on the clinical unit and (if possible) staff wearing appropriate PPE in rooms, not at desks, conference rooms)
6. Product Storage – if applicable (especially IECs if received directly)
7. MOCK procedure for administration of cellular therapy product:
  - a. Demonstrate:
    - i. Product receipt
    - ii. Verification of product identity and order to administer
    - iii. Thawing product or prep for administration
    - iv. Documentation of patient identity
    - v. Administration process
    - vi. Documentation
  - b. An adequate “mock procedure” could be a demonstration of a prior infusion using documentation, showing orders, labels, verification of identity, patient monitoring, notation related to adverse events, discard of empty container.

## Apheresis Collection Facility Tour

1. Apheresis Facility Space
  - a. Locked, limited access
  - b. Adequate space, size, and design
  - c. Space divided into defined areas to prevent improper labeling, mix-ups, contamination, or cross-contamination of products
  - d. Lighting, ventilation, and access to sinks and toilets
2. Product Collection Space (minimize risk of microbial contamination)
  - a. Confidential space for donor evaluation, consent
    - i. Include private rooms – isolation, negative pressure possible
    - ii. Include how each donor is identified (wrist bands)
    - iii. Include the doors vs curtains for other spaces
    - iv. One space/one donor/one product
3. Storage space – Include quarantined storage, shelves with labels, shelves off the floor and away from sprinkler system in ceiling; include collection kits and critical supplies
  - a. Include storage temperature/humidity
  - b. Include refrigerated storage for reagents if relevant
  - c. Include supply receipt process and visual examination and documentation
4. Inventory control that encompasses equipment, supplies, reagents, and labels
5. Product storage space until transferred to lab staff for transport (ready for distribution)– segregated, paperwork with product; clean; properly labeled product with ISBT label
  - a. For commercial IECs – space where product is packaged for pick up by courier for shipment to manufacturer
6. Training Records – collection staff and EVS
7. Records for facility cleaning and sanitation – How often are curtains cleaned and how are they cleaned or changed. (or have available on day of inspection)
8. Work sheets, forms, labels, logs – Can illustrate document identifiers, including how to be sure the current version is being used. Include where these are stored.
9. Equipment: adequate, Show Optias, Therakos, include calibration stickers on equipment for maintenance / calibration performed or due, if used. Show signs used for equipment out of service or calibration. Records available day of inspection for closer review.
  - a. Include emergency power
  - b. Include blood warmers

10. Access to emergency equipment and supplies; emergency care (treatment center, ICU)
11. Waste disposal
12. PPE: Gloves and protective equipment; Include all personal protective equipment
13. Transportation and shipping:
  - a. Usual transport methods and conditions for distribution from apheresis to processing facility. Include outer transport container and labels for internal transport.
  - b. If ship direct to third party manufacturer, include this process. Include shipping container with labels.
14. Labeling process: preprinted label storage; Print-on-demand label systems.
15. View MOCK Collection process. Include SOP that describes the process being shown on the video. Verify the following steps at a minimum:
  - a. Identification of donor
  - b. Verification of order to collect
  - c. Set up of collection machine, cleaning, verify compliance with maintenance, calibration
  - d. Verification of cleaning
  - e. Labeling process
  - f. Vital signs – process
  - g. Disconnection of product, temporary storage
  - h. Hand-off to transport personnel, transport, or preparation for shipping, as applicable

## Processing Facility Tour

1. Processing Facility Space
  - a. Locked, limited access
  - b. Adequate space, size, design
  - c. Space divided into defined areas to prevent improper labeling, mix-ups, contamination, or cross-contamination of products
  - d. Lighting, ventilation, and access to sinks and toilets
  - e. Facility cleaning and sanitation, maintain order/space for operations
  - f. Adequate equipment and materials for procedures performed
  - g. Operations to minimize risks to health and safety of employees, recipients, donors, visitors, and volunteers
  - h. Temperature, humidity, air quality, surface contaminant control and monitoring
2. Product Processing Space (minimize risk of microbial contamination)
  - a. Temperature, humidity, air quality (how monitored)
  - b. Controlled to prevent mix-ups, deterioration, cross-contamination, improper distribution
3. Supply Storage Space
  - a. Including Quarantined storage
  - b. Shelves clearly identified (e.g., received, approved)
  - c. Shelves off the floor and away from sprinkler system in ceiling
  - d. Include storage temperature/humidity
  - e. Include refrigerated storage for reagents if relevant
  - f. Include supply receipt process and visual examination and documentation
  - g. Temperature, humidity, air quality, surface contaminant control and monitoring
  - h. System for inventory control
  - i. Controlled to prevent mix-ups, deterioration, cross-contamination, improper distribution
  - j. Materials that adversely affect CT products stored in different refrigerator or freezer from CT products
4. Inventory control that encompasses equipment, supplies, reagents, and labels
5. Product Storage Space
  - a. Locked, limited access
  - b. Temperature, humidity, air quality, surface contaminant control and monitoring
  - c. O2 sensors, LN2 levels monitored

- d. Visible and audio alarms
  - e. Written instructions posted
  - f. System for Quarantine
6. Back-Up Storage
  7. Safety Manual
  8. Waste removal
  9. SOPs for staff to follow
  10. Labeling
    - a. ISBT 128
    - b. Placement of labels
    - c. Storage of labels
  11. Equipment
    - a. Maintenance and cleaning documented
    - b. Inspected for cleanliness
    - c. Evidence of calibration
    - d. Dry Shippers
  12. PPE: Gloves and protective equipment, include all personal protective equipment
  13. Records – storage location secure
  14. View MOCK processing procedure. Submit copy of the SOP being demonstrated.  
Demonstrate:
    - a. Receipt of product from collection facility
    - b. Verification of product integrity and labeling
    - c. Verification of processing order
    - d. Processing
    - e. Cryopreservation
    - f. Final labeling
    - g. Storage