Indiana University Health	**Original Creation Date:** 07/24/2023	**Publication Date:** Not Set
	Owner: Dave Schwering (Manager-Lab)	**Next Review:** Not Set
	Category: Labs AHC	
	Education: Level 4	
Approval Signatures: No Users		

Procedure Packaging and Shipment of Allogeneic Mononuclear Cells for the Manufacturing of Cytotoxic T-Cells for Clinical Protocols NYMC 579, NYMC 580, NYMC 581 and NYMC 590

I. PURPOSE

This SOP details the steps for packaging and shipment of the Apheresis products for NYMC 579, NYMC 580, NYMC 581, and NYMC 590 to a manufacturing facility for preparation for infusion.

II. SCOPE

This procedure applies to the packaging and shipment of NYMC Apheresis products for patients enrolled on IRB Protocols for studies NYMC 579, NYMC 580, NYMC 581, and NYMC 590. All Cellular Therapy Laboratory Technologists will follow this procedure

III. STATEMENTS/REQUIREMENTS

Any exceptions to this policy must be approved by the CTL Processing Facility Medical Director. Any exceptions that deviate from the study protocol must be approved by the Study PI.

- This procedure is used to support NYMC 579, NYMC 580, NYMC 581, and NYMC 590 protocols.
- All study forms are found in the corresponding confidential study binder.
- Always contact the study site manager for any questions or concerns.
- Any deviation that has the potential to impact the quality, purity, safety or testing of the NYMC product must be reported to the study site manager, the PI and CTL QA.
    - Deviations must be reported within 24 hours of discovery.

IV. DEFINITIONS

AABB: Association for the Advancement of Blood and Biotherapies

ADV: Adenovirus

AWB: Air Waybill

CMV: Cytomegalovirus

CTL: Cellular Therapy Laboratory

CIT: Indiana University Simon Comprehensive Cancer Center (Coordinating Center)

EBV: Epstein-Barr Virus

FACT: Foundation for the Accreditation of Cellular Therapy

FDA: Food and Drug Administration

HPC(A): Hematopoietic Progenitor Cells by Apheresis

ISBT: International information standard for coding and labeling of cell therapy products

NYMC 579: A Pilot Study in the Treatment of Refractory Adenovirus (ADV) Infection with Related Donor ADV Cytotoxic T-Lymphocytes in Children, Adolescents and Young Adult Recipients. The study was conducted at Children's Hospital of Philadelphia and New York Medical College.

NYMC 580: A Pilot Study in the Treatment of Refractory Cytomegalovirus (CMV) Infections with Related Donor CMV Specific Cytotoxic T-cells (CTLs) in Children, Adolescents and Young Adult Recipients.

NYMC 581: A Pilot Study in the Treatment of Refractory Epstein-Barr Virus (EBV) Infection with Related Donor EBV Cytotoxic T-Lymphocytes in Children, Adolescents and Young Adult Recipients.

NYMC 590: A Pilot Study in the Treatment of Refractory BK Infections with Related Donor BK Specific Cytotoxic T-cells (CTLs) in Children, Adolescents and Young Adult Recipients.

PI: Principal Investigator

RC: Research Coordinator

SOP: Standard Operating Procedure

V. EQUIPMENT/RESOURCES

Equipment:

Laminar Flow Hood

Tube Sealer

Scale

Microscope

VeriCor Transport Cooler

Shipping Container

UniCel ® DxH 600

Supplies:

Transfer Packs: 600mL, 300mL, 150mL

Luer lock syringes: 3mL, 10mL, 30mL, 60mL

Couplers-plasma and DMSO resistant

Needles 16 Gauge

1.2 mL Cryovials

12 x 75mm Polystyrene Tubes

Pipette Tips 1-200uL

Pipette Tips 200-1000uL Microscope Slides

22 x 22 mm Coverslips Thioglycolate Tubes

Sterile Alcohol Wipes

Biohazard and sharps disposal containers

Sterile, single use scissors

Sterile, Single use forceps

Storage basin

Test tubes

Apheresis Product

Bubble Wrap

Temperature Monitoring Device

Biohazard Bag

Absorbent Pads

'Do Not X-Ray' labels

Courier Shipping Documentation

VI. PROCEDURE

A. Receipt on MNC for further manufacturing.
   1. MNC, Apheresis cells will be collected in the IU Health Apheresis department.
      i. CTL will follow PST 005 Procedure Receipt of Cellular Therapy Products transfer of the MNC, Apheresis from Apheresis to CTL employees.
   2. Log product into F-001 CTL Activity Log .
   3. Transfer the MNC, Apheresis to a properly cleaned biological safety hood.
   4. Follow PM 018 Procedure Aseptic Technique for Cell Processing to obtain a sample for sterility culture, fungal culture, and cell counts.
      i. Document on F-013 Product Processing and Cryopreservation.
      ii. Flow analysis is not required for this protocol.
      iii. It is required to have a second technologist verify the calculations.
   5. Transfer the MNC, Apheresis product using aseptic technique to an appropriately sized transfer bag.
      i. Strip the tubing and heat seal.
         1. Make 3 heat seals and cut between the second and third seal.
            a. Two intact seals will remain on the portion of the tubing attached to the bag.
      ii. Weigh the final bag and document on the F-013.
   6. Label the bag following PST 008 Procedure: Product and Reagent Labeling.
      i. Use product code 1303 "MNC, Apheresis for Further Manufacturing"
      ii. Choose "Investigational Drug".
      iii. ABO and Rh must be filled in since this is an allogeneic product.
         1. Follow RT 009 Procedure Autologous and Allogeneic Product Immunohematological Testing.
      iv. Choose "*For Use by Intended Recipient(s) Only*" as the donation type.
      v. Enter Donor Last Name, First Name.
      vi. Enter Donor DOB and MRN.
         1. Enter the Donor Study ID next to the Donor MRN.
      vii. Enter Recipient Last Name, First Name.
      viii. Enter Recipient DOB and MRN.

1. Enter the Recipient Study ID next to the MRN.

ix. Enter the collection facility as IU Health Apheresis.
x. Enter the Processing facility as IU Health Cellular Therapy Laboratory.
xi. Enter the collection date and time.
xii. Enter the expiration date and time.
1. MNC, Apheresis product expires in 24 hours from the end of collection.
xiii. Follow the remainder of PST 008 Procedure: Product and Reagent Labeling to finish the label and have it checked by a second technologist.
1. Complete F-407 Verification of Fresh Apheresis Product Labeling: Matched Related Donor.

7. Finish the F-013 Product Processing and Cryopreservation with final bag data.
8. Make copies of the F-013 and IDMs to release with the product.
9. Coordinate with a CIT employee for the transfer of the product to their facility.
10. Log the product out of the F-001 CTL Activity Log .
i. Have the CIT employee sign the activity log so documentation of transfer is recorded.
11. Fill out the CIT chain of Custody form (provided by CIT).
i. Make a copy and retain in the patient's chart.

B. Billing

1. Billing will be entered into the donor's Cerner account using CTLP 002 Procedure Cellular Therapy Laboratory Billing

VII. CLINICAL SIGNIFICANCE/SPECIAL CONSIDERATIONS

The experimental product described in this protocol will be given to subjects with unmet medical needs for which there are no effective therapies known at this time.

VIII. REFERENCES

AABB Standards for Cellular Therapy Product Services, current edition.

FDA CFR Title 21, Part 1271 Human Cells, Tissues and Cellular and Tissue Based Products FACT Standards, current edition.

NYMC 579: A Pilot Study in the Treatment of Refractory Adenovirus (ADV) Infection with Related Donor ADV Cytotoxic T-Lymphocytes in Children, Adolescents and Young Adult Recipients. The study was conducted at Children's Hospital of Philadelphia and New York Medical College.

NYMC 580: A Pilot Study in the Treatment of Refractory Cytomegalovirus (CMV) Infections with Related Donor CMV Specific Cytotoxic T-cells (CTLs) in Children, Adolescents and Young Adult Recipients.

NYMC 581: A Pilot Study in the Treatment of Refractory Epstein-Barr Virus (EBV) Infection with Related Donor EBV Cytotoxic T-Lymphocytes in Children, Adolescents and Young Adult Recipients.

NYMC 590: A Pilot Study in the Treatment of Refractory BK Infections with Related Donor BK Specific Cytotoxic T-cells (CTLs) in Children, Adolescents and Young Adult Recipients.

IX. FORMS/APPENDICES

F-561b Allogeneic Product Description and Quality Certificate

Attachments:

CIT Product Chain of Custody Form

X. APPROVAL BODY

None

Procedure#

RCTL 026