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# Procedure Receipt, Storage and Dose Administration of Cytotoxic T-Cells for Clinical Protocols NYMC 579, NYMC 580, NYMC 581 and NYMC 590

Printed copies are for reference only. Please refer to the electronic copy for the latest version.

## I. PURPOSE

To provide guidelines to receive, prepare and distribute allogeneic IP products for patients receiving the NYMC Cytotoxic T-Cells research product.

## II. SCOPE

This procedure applies to the receipt and dose preparation of Cytotoxic T-Cells for patients approved for this product. All CTL Technologists will comply with this procedure.

## III. STATEMENTS/REQUIREMENTS

- Any exceptions to this procedure require approval by the PI and CTL Processing Facility Medical Director.
- This procedure is used in conjunction with:
  - **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.
- Always contact the NYMC Site Manager for any questions or concerns.
- Cytotoxic T-Cells will be delivered fresh by CTL Technologists and the product will be infused by Riley Nursing Staff or MD.

- Any deviation from the research protocol must be reported to Site Manager.
  - Deviations must be reported within 24 hours of discovery.

## IV. DEFINITIONS

**AABB:** Association for the Advancement of Blood and Biotherapies

**ADV:** Adenovirus

**CMV:** Cytomegalovirus

**CTL:** Cellular Therapy Laboratory

**CTI:** 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

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**PI:** Principal Investigator

**RC:** Research Coordinator

**SOP:** Standard Operating Procedure

## V. EQUIPMENT/RESOURCES

**Equipment:**

CIT Provided Transport Cooler

**Materials:**

Cytotoxic T-Cell Research Product

Non-sterile gloves and masks (on unit)

Y-type infusion set

CH-7755 Form (Stem Cell Infusion Assessment)

CH-2046 Form (Infusion of Hematopoietic Progenitor Cells)

## VI. PROCEDURE

**Product Receipt:**

- A. CTL will be notified in advance of delivery and will record the shipment date on the CTL calendar.
  - a. The product will be delivered fresh immediately after manufacturing and quality testing is completed.

- i. The fresh IP has an expiration of 6 hours from the end of manufacturing.
- B. CTL will follow all applicable instructions for receipt as described in the PST 005 [Procedure Receipt of Cellular Therapy Products](#)
- C. [F-415 Study IP Receipt Form](#) will be filled out at the time of unpacking of the shipping container.
  - a. This form will be kept in the recipients CTL chart.
- D. Any temperature excursions or product integrity deviations will be reported to the CTL Medical Director, CTL QA and to NYMC Study Coordinator immediately.
  - a. In the case of a temperature deviation, complete transfer of the product to appropriate temperature monitored storage prior to initiating any notifications.
  - b. The CTL Medical Director and NYMC PI will decide if the product is suitable or needs to be replaced.
- E. Log the IP into the [F-414 Cellular Therapy Laboratory Investigational Product Dispensing and Accountability Log](#)
  - a. List the appropriate protocol on the F-414.
- F. Log the product into the CTL Activity Log
  - a. List the appropriate protocol on the activity log entry

**Product Infusion:**

- A. Infusion will be scheduled by the Riley treating physician.
  - a. The fresh (non-cryopreserved) IP expires 6 hours after the end of manufacturing.
- B. Follow all applicable steps as described in SOP PM-004 [Procedure Related Allogeneic Infusion](#)
  - a. Obtaining infusion advice from the CTL Medical Director is not required.
    - i. The dose is determined by the protocol.
  - b. Cellular dose calculations are not required.
    - i. Enter "n/a" on the E-21 in appropriate section.
    - ii. If the manufacturer gives a total dose on the COA, enter onto the E-21 accordingly.
  - c. If the manufacturer gives the amount of DMSO, enter the DMSO on the E-21 and DMSO dose in the Cerner order.
    - i. If the DMSO volume is not provided enter "n/a".
  - d. In the event of a bag leak, notify the provider covering the infusion, the CTL Medical Director, CTL QA and the NYMC PI.
  - e. No post thaw testing of the product in the Cellular Therapy Laboratory will be performed.

## VII. CLINICAL SIGNIFICANCE/ SPECIAL CONSIDERATIONS

None

## 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

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## **IX. FORMS/APPENDICES**

F-001 CTL Activity Log F-045 LN2 Shipper and Water Bath QC

F-415 Study IP Receipt Form

CH-2046 Cellular Therapy Lab Infusion Form

CIT Chain of Custody:

CIT Certificate of Analysis

## **X. APPROVAL BODY**

None

## **Procedure Number**

RCTL 027