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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

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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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:

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