Indiana University Health

CTL TEAM MEETING

8/2024

Housekeeping Items

- Cerner upgrade
- Send WAMBIs at least monthly!
- Wash your hands! We are auditing.
- FACT is coming 8/30.

Notification for Deviations and Non-conformities

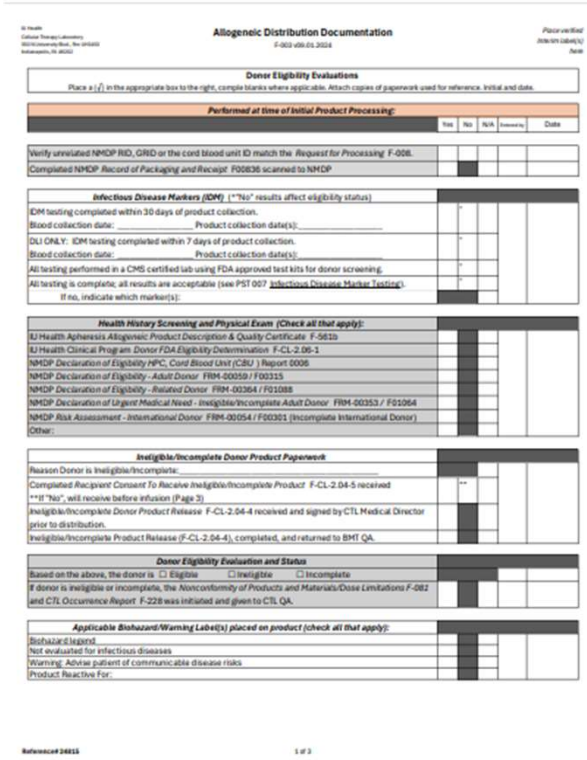
- When contacting me, Diagnotes is the least reliable, it doesn't always alert me. Feel free to try diagnotes but follow up with a text/call to let me know to look at it if I haven't responded promptly. Email pops up on my phone, feel free to text, and call if it's really important.
- Always include transplant physician on Deviations and Non-conformities. It is a FACT requirement to show that the Medical Director and Transplant Physician came to an agreement.
  - Print and include emails/diagnotes with F-081 and F-200 submissions
- Do not proceed without getting approval

Staffing/Training Updates

- Please keep an eye out for annual competencies
  - Set to be released Sept of 2024
  - Start gathering data now if possible.

Updated Forms – F-003

New version of F-003 goes into effect 9.1.2024



Allogeneic Distribution Documentation

F-003 v09.01.2024

Place verified

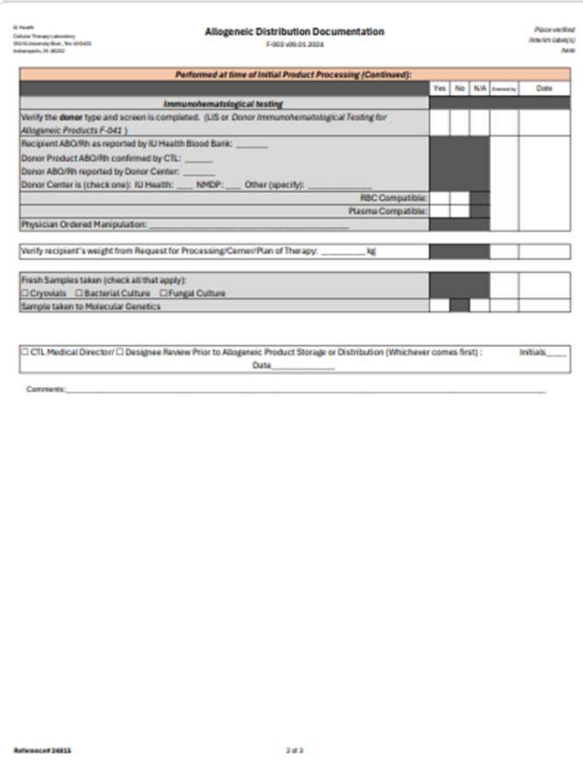
Donor Eligibility Evaluations

Place a (√) in the appropriate box to the right, compile blanks where applicable. Attach copies of paperwork used for reference. Initial and date.

Performed at time of Initial Product Processing:

	Yes	No	N/A	Entered by	Date
Verify unrelated NMDP RID, GRID or the cord blood unit ID match the *Request for Processing* F-008.					
Completed NMDP *Record of Packaging and Receipt* F00836 scanned to NMDP					
Infectious Disease Markers (IDM) (**"No" results affect eligibility status)					
IDM testing completed within 30 days of product collection.					
Blood collection date: _____ Product collection date(s):_____					
DLI ONLY: IDM testing completed within 7 days of product collection.					
Blood collection date: _____ Product collection date(s): _____					
All testing performed in a CMS certified lab using FDA approved test kits for donor screening.					
All testing is complete; all results are acceptable (see PST 007 Infectious Disease Marker Testing).					
If no, indicate which marker(s):					
Health History Screening and Physical Exam (Check all that apply):					
IU Health Apheresis *Allogeneic Product Description & Quality Certificate* F-561b					
IU Health Clinical Program *Donor FDA Eligibility Determination* F-CL-2.06-1					
NMDP *Declaration of Eligibility HPC, Cord Blood Unit (CBU)* Report 0006					
NMDP *Declaration of Eligibility - Adult Donor* FRM-00059 / F00315					
NMDP *Declaration of Eligibility - Related Donor* FRM-00364 / F01088					
NMDP *Declaration of Urgent Medical Need - Ineligible/Incomplete Adult Donor* FRM-00353 / F01064					
NMDP *Risk Assessment - International Donor* FRM-00054 / F00301 (Incomplete International Donor)					
Other:					
Ineligible/Incomplete Donor Product Paperwork					
Reason Donor is Ineligible/Incomplete:_____					
Completed *Recipient Consent To Receive Ineligible/Incomplete Product* F-CL-2.04-5 received					
**If "No", will receive before infusion (Page 3)					
Ineligible/Incomplete Donor Product Release F-CL-2.04-4 received and signed by CTL Medical Director prior to distribution.					
Ineligible/Incomplete Product Release (F-CL-2.04-4), completed, and returned to BMT QA.					
Donor Eligibility Evaluation and Status					
Based on the above, the donor is ☐ Eligible ☐ Ineligible ☐ Incomplete					
If donor is ineligible or incomplete, the *Nonconformity of Products and Materials/Dose Limitations F-082* and *CTL Occurrence Report* F-228 was initiated and given to CTL QA.					
Applicable Biohazard/Warning Label(s) placed on product (check all that apply):					
Biohazard legend					
Not evaluated for infectious diseases					
Warning: Advise patient of communicable disease risks					
Product Reactive For:					

Reference# 24015 1 of 3



Allogeneic Distribution Documentation

F-003 v09.01.2024

Place verified

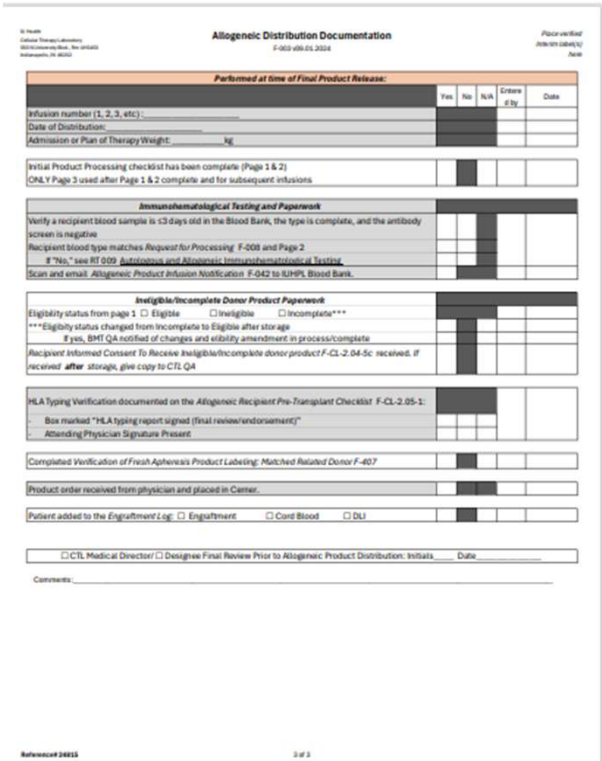
Performed at time of Initial Product Processing (Continued):

	Yes	No	N/A	Entered by	Date
Immunohematological testing					
Verify the **donor** type and screen is completed. (LIS or *Donor Immunohematological Testing for Allogeneic Products F-041*)					
Recipient ABO/Rh as reported by IU Health Blood Bank: _____					
Donor Product ABO/Rh confirmed by CTL: _____					
Donor ABO/Rh reported by Donor Center: _____					
Donor Center is (check one): IU Health: ___ NMDP: ___ Other (specify): _____					
RBC Compatible:					
Plasma Compatible:					
Physician Ordered Manipulation: _____					
Verify recipient's weight from Request for Processing/Cerner/Plan of Therapy: _____kg					
Fresh Samples taken (check all that apply):					
☐Cryovials ☐Bacterial Culture ☐Fungal Culture					
Sample taken to Molecular Genetics					

☐ CTL Medical Director/ ☐ Designee Review Prior to Allogeneic Product Storage or Distribution (Whichever comes first) : Initials____ Date_____

Comments:_____

Reference# 24015 2 of 3



Allogeneic Distribution Documentation

F-003 v09.01.2024

Place verified

Performed at time of Final Product Release:

	Yes	No	N/A	Entered by	Date
Infusion number (1, 2, 3, etc):_____					
Date of Distribution:_____					
Admission or Plan of Therapy Weight: _____kg					
Initial Product Processing checklist has been complete (Page 1 & 2) ONLY Page 3 used after Page 1 & 2 complete and for subsequent infusions					
Immunohematological Testing and Paperwork					
Verify a recipient blood sample is ≤3 days old in the Blood Bank, the type is complete, and the antibody screen is negative					
Recipient blood type matches *Request for Processing* F-008 and Page 2					
If "No," see RT 009 Autologous and Allogeneic Immunohematological Testing					
Scan and email *Allogeneic Product Infusion Notification* F-042 to IUHPL Blood Bank.					
Ineligible/Incomplete Donor Product Paperwork					
Eligibility status from page 1 ☐ Eligible ☐Ineligible ☐Incomplete***					
***Eligibility status changed from Incomplete to Eligible after storage					
If yes, BMT QA notified of changes and eligibility amendment in process/complete					
Recipient Informed Consent To Receive Ineligible/Incomplete donor product F-CL-2.04-5c received. If received **after** storage, give copy to CTL QA					
HLA Typing Verification documented on the *Allogeneic Recipient Pre-Transplant Checklist* F-CL-2.05-1:					
Box marked "HLA typing report signed (final review/endorsement)"					
Attending Physician Signature Present					
Completed *Verification of Fresh Apheresis Product Labeling: Matched Related Donor F-407*					
Product order received from physician and placed in Cerner.					
Patient added to the *Engraftment Log*: ☐ Engraftment ☐ Cord Blood ☐ DLI					

☐CTL Medical Director/☐ Designee Final Review Prior to Allogeneic Product Distribution: Initials____ Date_____

Comments:_____

Reference# 24015 3 of 3

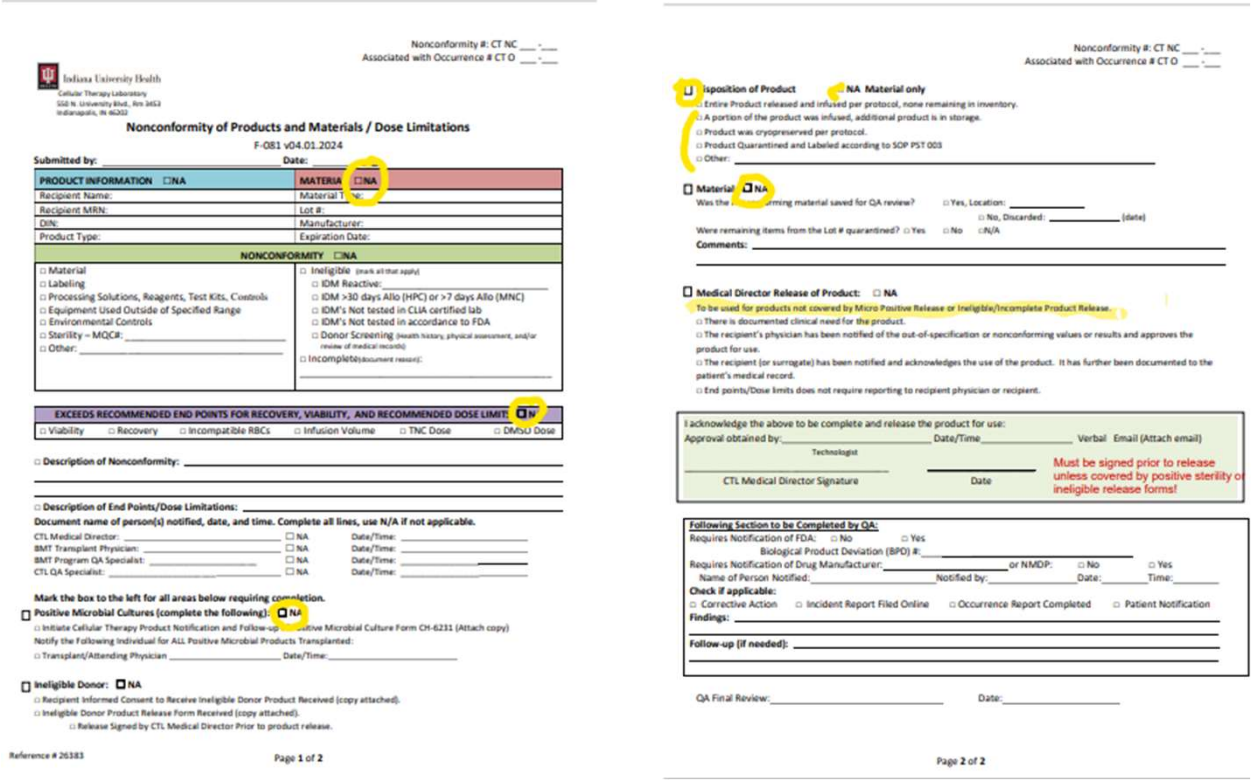
Indiana University Health

Lunches

PLEASE BE PROACTIVE ABOUT TAKING LUNCHES

- It's not OK to skip lunch if someone else is available to cover. Someone can start your mid sample so you can get a lunch for example.

Documentation



Nonconformity #: CT NC ___-___
Associated with Occurrence # CT O ___-___

Indiana University Health
Cellular Therapy Laboratory
550 N. University Blvd., Rm 3653
Indianapolis, IN 46202

Nonconformity of Products and Materials / Dose Limitations

F-081 v04.01.2024

Submitted by: _____ **Date:** _____

PRODUCT INFORMATION ☐NA	MATERIAL ☐NA
Recipient Name:	Material Type:
Recipient MRN:	Lot #:
DIN:	Manufacturer:
Product Type:	Expiration Date:

NONCONFORMITY ☐NA	
☐ Material ☐ Labeling ☐ Processing Solutions, Reagents, Test Kits, Controls ☐ Equipment Used Outside of Specified Range ☐ Environmental Controls ☐ Sterility – MQC#: _____ ☐ Other: _____	☐ Ineligible (mark all that apply) ☐ IDM Reactive: _____ ☐ IDM >30 days Allo (HPC) or >7 days Allo (MNC) ☐ IDM's Not tested in CLIA certified lab ☐ IDM's Not tested in accordance to FDA ☐ Donor Screening (Health history, physical assessment, and/or review of medical records) ☐ Incomplete(document reason): _____

EXCEEDS RECOMMENDED END POINTS FOR RECOVERY, VIABILITY, AND RECOMMENDED DOSE LIMIT: ☐N

☐ Viability ☐ Recovery ☐ Incompatible RBCs ☐ Infusion Volume ☐ TNC Dose ☐ DMSO Dose

☐ **Description of Nonconformity:** _____

☐ **Description of End Points/Dose Limitations:** _____

Document name of person(s) notified, date, and time. Complete all lines, use N/A if not applicable.

CTL Medical Director: _____ ☐ NA Date/Time: _____
BMT Transplant Physician: _____ ☐ NA Date/Time: _____
BMT Program QA Specialist: _____ ☐ NA Date/Time: _____
CTL QA Specialist: _____ ☐ NA Date/Time: _____

Mark the box to the left for all areas below requiring completion.

☐ **Positive Microbial Cultures (complete the following): ☐ NA**
☐ Initiate Cellular Therapy Product Notification and Follow-up ...itive Microbial Culture Form CH-6231 (Attach copy)
Notify the Following Individual for ALL Positive Microbial Products Transplanted:
☐ Transplant/Attending Physician _____ Date/Time: _____

☐ **Ineligible Donor: ☐ NA**
☐ Recipient Informed Consent to Receive Ineligible Donor Product Received (copy attached).
☐ Ineligible Donor Product Release Form Received (copy attached).
☐ Release Signed by CTL Medical Director Prior to product release.

Reference # 26383 Page 1 of 2

Nonconformity #: CT NC ___-___
Associated with Occurrence # CT O ___-___

☐ **Disposition of Product ☐ NA Material only**
☐ Entire Product released and infused per protocol, none remaining in inventory.
☐ A portion of the product was infused, additional product is in storage.
☐ Product was cryopreserved per protocol.
☐ Product Quarantined and Labeled according to SOP PST 003
☐ Other: _____

☐ **Material ☐ NA**
Was the ...rming material saved for QA review? ☐ Yes, Location: _____
☐ No, Discarded: _____ (date)
Were remaining items from the Lot # quarantined? ☐ Yes ☐ No ☐ N/A
Comments: _____

☐ **Medical Director Release of Product: ☐ NA**
To be used for products not covered by Micro Positive Release or Ineligible/Incomplete Product Release.
☐ There is documented clinical need for the product.
☐ The recipient's physician has been notified of the out-of-specification or nonconforming values or results and approves the product for use.
☐ The recipient (or surrogate) has been notified and acknowledges the use of the product. It has further been documented to the patient's medical record.
☐ End points/Dose limits does not require reporting to recipient physician or recipient.

I acknowledge the above to be complete and release the product for use:
Approval obtained by: _____ Date/Time _____ Verbal Email (Attach email)
Technologist

_____ _____
CTL Medical Director Signature Date

Must be signed prior to release unless covered by positive sterility o... ineligible release forms!

Following Section to be Completed by QA:
Requires Notification of FDA: ☐ No ☐ Yes
Biological Product Deviation (BPD) #: _____
Requires Notification of Drug Manufacturer: _____ or NMDP: ☐ No ☐ Yes
Name of Person Notified: _____ Notified by: _____ Date: _____ Time: _____
Check if applicable:
☐ Corrective Action ☐ Incident Report Filed Online ☐ Occurrence Report Completed ☐ Patient Notification
Findings: _____
Follow-up (if needed): _____

QA Final Review: _____ Date: _____

Page 2 of 2

Make sure all sections are completed or marked as N/A

Indiana University Health

Quick Drill Building Lockdown

- Scenario: Using the IU Health AHC Emergency Procedure Guide (EPG), discuss how department staff would respond if emergency access control alerts were received via overhead announcement and IU Health Emergency Alert

Indiana University Health

Values Acknowledgments: Purpose, Excellence, Compassion, Team

Thanks to Jennifer for staying to finish the Peridox on the hoods after our recent uptick in positive sterility results.

Thanks to everyone who has helped with the recent FDA and upcoming FACT inspections.

Questions???

Indiana University Health