# Applicable Laboratory(s)):

North Carolina Baptist Hospital (NCBH)

Lexington Medical Center (LMC)

Davie Medical Center (DMC)

Wilkes Medical Center (WMC)

High Point Medical Center (HPMC)

Westchester

Clemmons

# Policy Purpose

The purpose of this policy is to provide instructions regarding the receipt, storage, preparation, and administration of investigational cold stored platelets (CSP). This study is a phase 3, multicenter, international, randomized, partial blind, adaptive, non-inferiority, storage duration ranging trial in adult and pediatric patients undergoing cardiac surgery.

# Scope

This policy applies to Blood Bank Staff and management.

# Definitions

1. Policy: As defined in the Policy on Creating and Amending Policy, a statement of principle that is developed for the purpose of guiding decisions and activities related to governance, administration, or management of care, treatment, services or other activities of WFBH.  A policy may help to ensure compliance with applicable laws and regulations, promote one or more of the missions of WFBH, contain guidelines for governance, and set parameters within which faculty, staff, students, visitors and others are expected to operate.
2. WFBH Lab System: Wake Forest Baptist Lab System is a health system that includes Wake Forest Baptist Medical Center and all affiliated organizations including Wake Forest University Health Sciences (WFUHS), North Carolina Baptist Hospital (NCBH), Lexington Medical Center (LMC), Davie Medical Center (DMC), Wilkes Medical Center (WMC), High Point Medical Center (HPMC), Lab at Westchester and Lab at Clemmons.

C. CSP: Cold Stored Platelet

D. uCCC: unblinded Clinical Coordination Center

E. EDC: Electronic Data Capture System

F. REDCap Cloud (RCC): EDC used for CHIPS

# Policy Guidelines

1. Study Platelets
2. Techs working CP bench should check the BB calendar at the start of their shift for any potential CHIPs study patients and alert FD staff of potential orders for these cases.
3. Study platelets are available during surgery or up to 24 hours after surgery or admission to ICU (which ever is later).
4. If a patient uses a platelet during surgery and is admitted to ICU. The 24 hour clock to continue with study platelets starts at the time of issue of the FIRST platelet.
5. If a patient does not receive platelets in the OR but does receive their first platelet within 24 hours of their CVICU admission, they should get study plts. They are then eligible for study plts for 24 hours from the time of issue of that FIRSTplatelet.
6. If apatient needs their FIRST platelet > 24 hours after their CVICU admission, they should NOT get study plts. Staff should follow routine SOP to fill the order.
7. Cold Stored Platelets (CSP)
8. Investigational study product (CSP) will be collected through apheresis collection by a US licensed or registered blood collection facility and contain between 200-425mL of apheresis platelets.
9. Cold stored units will be tested for HIV (I/II), HCV, HBV, HTLV, WNV, T.cruzi, and babesia per FDA requirements.
10. CSP will not be tested for bacteria since they will be placed in 1-6°C conditions within 8 hours of collection or within 24 hours for pathogen-reduced platelets.
11. Due to short life of apheresis platelets, CSP must be ordered on-demand. uCCC will contact Blood bank staff to place an order for CSP if the study subject randomizes to CSP.
12. CSP can be irradiated per standard SOP as required per patient
13. Patients will be randomized at a 2:1 ratio to receive 4°C platelets (CSP) or 22°C platelets.
14. Randomization may take place up to 30 days prior to initial transfusion once a potential study participant has been identified and has consented.
15. Once a patient has randomized, unblinded study members will receive an email (sent to Blood Bank Staff) stating that the patient has been randomized.
16. Blood Bank staff shall log onto the EDC to determine the assigned arm (4°C platelets “cold” vs. 22°C platelets “warm”).
17. Randomized status should NOT be shared with the PI, study staff, or patient. Only the unblinded members (blood bank and uCCC staff) are privy to this information.
18. With the exception of the blood bank staff or transfusionist who may become unblinded, all other hospital and study personnel will be blinded to the study platelet assignment (4°C or 22°C platelets) during the course of the study

k. The uCCC will review and confirm the use and inventory of the study platelets

throughout the study.

1. The uCCC will arrange for investigational product supply based on participant randomization.
2. Upon completion of the study, the uCCC will arrange for destruction or return of all investigational study platelets and obtain copies of the investigational supply and inventory records and documentation of destruction or disposal.
3. uCCC Contact Information:

|  |  |  |
| --- | --- | --- |
| Name | Email | Phone |
| Unblinded CCC | [CHIPS\_unblinded@wustl.edu](mailto:CHIPS_unblinded@wustl.edu) |  |
| Meghan Huff | meghanhuff@wustl.edu | 618-578-9309 |
| Taegen Sullivan | [taegen@tessaphamaceutics.com](mailto:taegen@tessaphamaceutics.com) | 269-806-8579 |

2. Standard Room Temperature Platelets

1. Standard room temperature platelets will come from general inventory.

B. Storage of CSP

1. CSP shall be stored at 1-6°C on a flat, solid surface in a single layer with the ISBT label facing down.
   1. Any temperature excursions shall be reported to the uCCC and affected CSP shall be quarantined until the uCCC notifies staff in writing that the CSP can be used.
2. CSP should NOT be manipulated during storage (no agitation).
3. At the beginning of the study, CSP will have an expiration of 7 days.
4. The CSP expiry may change over time with a maximum of 21 days during the course of the study.
5. Blood bank will be notified about any changes to records, shelf-life, and storage conditions that are adjusted during the trial. These changes will apply to units already in production and/or in inventory.
6. CSP that are issued to the OR/ICU and not transfused may be returned to the blood bank if the unit(s) have not been out for more than 4 hours.
7. CSP units that are returned within the 4 hours window may be placed back into inventory for future use.
8. CSP units that are returned outside of the 4 hour window must be discarded.
9. Disposition of units must be noted in both Sunquest and the EDC
10. Time out of the refrigerator will be documented on the Accountability Log

*Refer to Attachment 3:: Accountability Log*

1. Cold platelets should be remain in the refrigerator until issued. (leave in fridge after selection.)

C. Adverse Event Reporting

1. All serious transfusion related events should be reported to the blood bank.
2. All events involving 22°C platelets should follow SOP and blood bank will notify the blood supplier if applicable.
3. All events involving 4°C platelets should follow SOP and be reported to the uCCC team who will notify the blood supplier if applicable.
4. Any transfusion reaction reports should be uploaded to the EDC

*Refer to Attachment 2: eCRF Completion Guidelines Blood Bank 4.3 Transfusion Reaction*

# Procedure

I. Order and Receipt of CSP: **Management/Designated Personnel Tasks (black),** **Lab Staff tasks (Red)**

| **STEPS** | **INSTRUCTIONS** |
| --- | --- |
| **1.0** | Notification that a patient had been randomized will be sent to all blood bank staff. Add message to BAD File: “CHIPS Protocol Patient” Add patient to BB calendar. |
| **2.0** | Log in to EDC: REDCap Cloud to determine to which arm of the study the patient had been randomized (room temp or cold).   1. Choose the Chilled Platelet Study 2. Select Study Site: Wake Forest 3. Select subjects from the left column 4. Choose the subject 5. Select the form “Unblinded Treatment Assignment” under the Blood Bank tab.   *Refer to Attachment 2: eCRF Completion Guidelines—Blood Bank 4.1 Treatment Arm*   1. Mark the instrument as complete in the EDC after review |
| **3.0** | If patient randomizes to RT 22°C platelets add comment to Sunquest (see below).  a. Add date of expected surgery as a comment |
| **4.0** | If patient randomizes to cold stored platelets (CSP) add comment to Sunquest (see below). The uCCC will contact BB and facilitate ordering cold stored platelets.   1. Add date of expected surgery as a comment 2. A total of 5 platelets will be obtained (from current stock or blood supplier) for each study participant that randomizes to CSP |
| **5.0** | Upon receipt of CSP: Outer shipping container should be examined for damage. |
| **6.0** | If there is damage to the outer container, the inner box should be removed and examined for damage. |
| **7.0** | Report any damage to the shipping system to [CHIPS\_unblinded@wustl.edu](mailto:CHIPS_unblinded@wustl.edu) Also notify management in a QA |
| **8.0** | Inspect product and compete packing slip (Attachment 1). Place packing slip in management mailbox outside office door. |
| **9.0** | uCCC staff shall be notified immediately if there is any damage to the CSP or if they arrive out of temperature (*Refer to section B*). |
| **10.0** | Receive the units in the EDC and scan a copy of the packing slip to the unblinded coordinator.  *Refer to Attachment 2: eCRF Completion Guidelines—Blood Bank* |
| **11.0** | Receive the units into BB LIS. |

II. Use and Issuing of Study Platelets

| **STEPS** | **INSTRUCTIONS** |
| --- | --- |
| **1.0** | Obtain ordered units from either 22°C or 4°C storage as indicated by randomization process  in the PCW.  a. If 22°C (RT) platelets, proceed to step **2.0**  b. If 4°C platelets, proceed to step **4.0** |
| **2.0** | **For 22°C (RT) platelets**   1. Make copy of platelet bag label 2. Keep copy with plt order requisition |
| **3.0** | Prior to selection, change the expiration date of plt to be selected to the following day at 2359, **unless the units expire earlier**.   1. Create and apply updated ISBT label.    * 1. To ensure the clinical team cannot identify the platelet as a CSP based on expiration date.      2. To ensure unblinded information is not transferred into the EMR.      3. E code is not considered unblinded information as most people cannot identify   a component type based on this information.   1. Proceed to step **7.0** |
| **4.0** | **For 4°C platelets**   1. Choose platelet(s) from designated “Cold platelet” area. 2. Observe units for signs of film or micro aggregate formation. 3. CSP may develop a slight film during storage. 4. To dissipate film, manually manipulate the bag in a see-saw motion, tilting each side up and down for 60 seconds prior to issuing the product. |
| **5.0** | Make a copy of the 4°C platelet label   1. Keep copy with plt order requisition |
| **6.0** | Prior to selection, change the expiration date of plt to be selected to the following day at 2359, **unless the units expire earlier**.   1. Create and apply updated ISBT label. 2. To ensure the clinical team cannot identify the platelet as a CSP based on expiration date. 3. To ensure unblinded information is not transferred into the EMR. 4. E code is not considered unblinded information as most people cannot identify   a component type based on this information.   1. Proceed to step **7.0** |
| **7.0** | Apply the “FOR INVESTIGATIONAL USE ONLY” sticker to all platelets including any 22°C platelets selected. This is typically placed at the bottom left hand corner of the label, below the blinding sticker that obscures storage temp.    **Note: Most CSP will come with the “FOR INVENSTIGATIONAL USE ONLY” wording incorporated into the ISBT label; this should be covered with a sticker as it could be unblinding if only some of the study platelets have the sticker. The idea is or all the pltatlets issued to look the same”** |
| **8.0** | Select platelet in Sunquest per SOP. |
| **9.0** | Issue platelets in Sunquest per SOP and place in standard RT cooler for transport to OR/ICU.   1. Move COPY of bag label and keep with ISSUE SLIP on clip at FD 2. If platelets are selected prior to issue, cold plts should be stored in the fridge until they are picked up by OR/ICU staff. |
| **10.0** | Add appropriate CHIPS comment in Sunquest indicating the date/time the first CSP unit is issued to the patient. |
| **11.0** | Each study participant may receive up to 6 units in a 24-hour period.   1. If patient randomizes to CSP: 2. Date/time of the first CSP unit issued will be documented Sunquest in the BAD file. 3. When more orders arrive for platelets, techs will check Sunquest to determine if more CSP can be issued (max of 6 in 24 hours). 4. 8 platelets or >24 hours after the first unit is issued, CSP shall no longer be selected or issued and 22°C platelets will be selected from general inventory 5. After 24 hours or 8 platelets (which ever comes first), blinding labels are no longer   needed.     * **Note:** While 8 CSP can be given to each patient that randomizes to CSP, inventory numbers may be insufficient to provide 8. When CSP supplies have been exhausted, the additional study platelets should be 22°C platelets that follow blinding protocols. * **If MTP is called on a study patient while they are within their 24 hour platelet window, they are automatically OUT of the study and normal MTP procedures should be followed.**   b. If patient randomizes to 22°C platelets:  1. Blinding labels need to be on the first 6 platelets issued within 24 hours.  2. After 24 hours or 6 platelets (which ever comes first), blinding labels are no longer  needed. |
| **12.0** | Information about all platelets received by study participants within 72 hours of issue of the first platelet will be logged into the EDC.   1. The Clinical Team will notify the Blood Bank via email with the date and time the patient’s study window closes. Upon receipt of email, the FD tech present will 2. PRINT the email 3. Add comment in Sunquest to Bad File  * Copy and paste the date and time the study window CLOSES from the email into the Note to Tech. * F12 > Y > F12 to save added information.  1. Boldy document the END Date and Time of the study period AT THE TOP OF THE PRINTED EMAIL. Place on Bridge. 2. **In the event a patient is NOT transfused plts in OR, BUT IS transfused within 24 hours of CVICU admission, BB will receive another email from the clinical team with a NEW window close time (24 hours from the time of the 1st platelet transfusion.) Repeat steps 1-3 as with the first email.** 3. Once the window to receive study platelets has closed, the XM tech will take the email from the bridge, remove ALL CHIPS related comments from the patient’s BAD **File.Note: only techs with admin privaleges can remove. Give to mgmt. to remove if no qualified tech is in the building.** 4. Initial and date the email once completed and place in management box for review. 5. Management will determine 72 hour window and log all plts into the EDC accordingly.    * Example; Patient admitted to ICU on 3/15/2022 at 0800; patient received first platelet in the ICU at 1832 on 3/15/2022:   **’72 hours post platelet administration: 03/18/2022 1832’**  OR   * Example: Patient received first platlet in OR on 3/15/2022 at 0800; Patient admitted to ICU on 3/15/2022 at 1900:   **Patient ’72 hours post ICU admission: 3/19/2022 1900’**   1. Consult management with questions if clarification is needed. |
| **8.0** | Record all pertinent information on Accountability Log  *Refer to Attachment 3: Accountability Log* |
| **9.0** | All platelets issued to study participants must be tracked in the EDC.   1. Log into EDC and document issue date/time 2. If 22°C platelets were issued, they must be entered into the EDC before documenting their issue date/time   c. There are two places in the EDC to track platelets:  Platelet Tracker/Dashboard. This is where running inventory of CSP is maintained.  Patient blood bank forms. This is where the treatment assignment, data for all platelets transfused for 72 hours from first study platelet, and transfusion reactions are uploaded.  *Refer to Attachment 2: eCRF Completion Guidelines—Blood Bank 4.2 Platelet Units Transfused*  Blinded team members will enter transfusion start/stop times and volumes for all blood products administered. |
| **11.0** | In the unlikely event that CSP platelets are administered for non-investigational purposes, the uCCC must be notified immediately. |

III. Returning Study Platelets

1. 22°C platelets that are issued and not transfused can be returned to inventory per SOP.
2. Using the copy of the original label, return the unit to its original expiration date, print new label and relabel/label check.
3. Ensure removal of investigational study product sticker before return to regular inventory.
4. 4°C platelets (CSP) may be returned to the blood bank if the unit(s) have not been out of the refrigerator for more than 4 hours. If acceptable,
5. Using the copy of the original label, return the unit to its original expiration date, print new label, relable and label check.
6. Ensure removal of investigational study product stickers.
7. Return the units electronically and placed back into the refrigerator for use on other eligible study participants.
8. Complete Attachment 2: Accountability Log

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1. Update unit status in EDC.

*Refer to Attachment 2: eCRF Completion Guidelines—Blood Bank*

G. Shipping Systems

1. CSP will be transported in containers provided by CHIPS that are validated to maintain temperature of product between 1-10°C for up to 48 hours.
2. To ensure the platelets remained within temperature range, platelets will only be accepted and used in the study if the CSP arrives within 48 hours of packing.
3. Tech receiving product will complete the packing form which will include the time of packaging.

*Refer to Attachment 1: Clinical Supplies Distribution Request Form (CSDRF)*

b. If CSP has been in transit for greater than 48 hours, staff will quarantine the platelets and contact the uCCC.

3. CSP may need to be shipped to another site depending on inventory and expiration.

1. The shipping containers and cooling cassettes should be kept by the blood bank until needed to ship product to an alternate clinical site or until requested to ship back to the depot.
2. 4 coolant cassettes are needed to ship out CSP
3. 2 yellow coolant cassettes should be stored at 1-6°C
4. 2 blue coolant cassettes should be stored at -20°C to be conditioned for next use.
5. The coolant cassettes must be placed in the respective chambers (refrigerator/freezer) for a minimum of 24 hours prior to packing
6. Blood Bank should keep 2-3 cooler sets charged at all times.
7. Store MaxQ coolers in secure location to keep them from being discarded.
8. If any damage to the container, contact the uCCC team for replacement parts. Replacement parts take approximately 1 week to arrive.
9. Shippers should be packed according to the pack-out schematic and procedure below:

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| **STEPS** | **INSTRUCTIONS** |
| --- | --- |
| **1.0** | Remove one PCM5 Cassette (blue) from the freezer and place in bottom of the shipper. |
| **2.0** | Remove one PCM5 Cassette (yellow) and place directly on top of the frozen PCM5 Cassette. |
| **3.0** | Load the payload (plts) into a liner bag and place it on top of the refrigerated PCM5 Cassette  Note: use adsorbent pads inside the leak proof liner bag at the top and bottom of the platelet unit stack. Lay the units flat inside the liner bag. |
| **4.0** | Take the second refrigerated PCM5 Cassette (yellow) and place it directly on top of the liner bag containing the payload units. |
| **5.0** | Lay the last PCM5 Cassette from the freezer (blue) on top of the refrigerated PCM5 Cassette and fill any remaining space with a bubble wrap filler material.  Note: the platelets should never come in direct contact with the frozen PCM5 Cassettes |
| **6.0** | If packing less than maximum units, follow the same steps above but fill any remaining space with bubble wrap or similar dunnage material to avoid payload or coolant shifting during transit. |
| **7.0** | Complete the Clinical Supplies Distriubution Request Form and place it in a zip top bag between the coolant cassettes and the lid of the box. |
| **8.0** | Close the container lid and seal tightly with packing tape. The container is now ready for shipment. |
| **9.0** |  |

# Literature References:

# Related Policies/Procedures in Navex:

# Attachments/Linked Documents in Title 21:

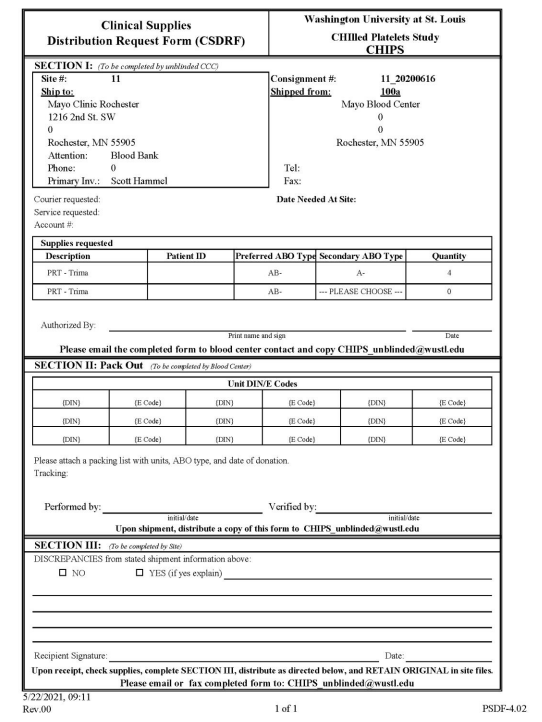
Attachment 1: Clinical Supplies Distribution Request Form (CSDRF)

Attachment 2: eCRF Completion Guidelines—Blood Bank

Attachment 3: Accountability Log

# Revision Dates: Review Change Summary as Represented in Title 21.

Attachment 1: Clinical Supplies Distribution Request Form (Example)



Attachment 3: Accountability Log

