**Purpose:**

To provide instructions for ordering, receiving, storing, and selecting COVID-19 Convalescent plasma (CP) collected from patients who recovered from COVID-19 infection for transfusion to patients who are critically ill with COVID-19 and are enrolled in the Passive Immunity Trial for Our Nation (PassItOn) Convalescent Plasma Study.

**Policy:**

* Study patients are consented by the physician or principle investigator (PI).
* CP components are stored at ≤ -18 C segregated from standard plasma units to prevent inadvertent use by non-study patients
* CP components are automatically ordered and shipped from Blood Assurance or their contracted vendor as patients are enrolled.
* Patient orders for CP are placed by the PI or Study Coordinator in Epic with a comment regarding PassItOn study.
* Each enrolled patient will be issued only one unit of CP. If CP is not available, contact research coordinator and notify of delay.
* Transfusion reactions related to the transfusion of CP will be reported to HMC TSL and worked up per standard policy. TSL Medical Director/designee will consult with Study Coordinator and bedside RN.

**Procedure notes and limitations:**

* CP components from Blood Assurance are to be allocated and issued only to patients approved and enrolled in clinical study.
* Units thawed and not transfused to the intended participant will be refrigerated and used on the next ABO Compatible enrolled participant. Place unit on appropriate shelf and notify the research coordinator.

**Principle**

PassItOn is a multi-center, blinded, placebo-controlled randomized trial being performed to compare the effect of convalescent plasma versus placebo on clinical outcomes.

CP components are collected from recovered patients with antibody quantification above the neutralizing threshold and who are otherwise eligible for blood donation. CP components will be labeled with the following statement; “CAUTION: New Drug-Limited by Federal Law to Investigational Use”.

COVID-19 infection can present with severe and life threating symptoms. At this time there are several therapeutic options, but no definitive treatment has been determined. The goal of the study is to determine if there is any clinical therapeutic advantage in providing patients who are critically ill with COVID-19, with plasma from patients who recovered from COVID-19 infection with high titer antibodies. The rationale is to provide passive immunity from recovered patients to sick patients.

Note: the only individuals that are knowledgeable about the treatment assignment are the VCC Data Specialist and designated Clinical Research Associate, the study statistician (unblinded), and the study personnel administering the plasma or placebo product. Patients, families, and outcome assessors will be blinded to treatment arm assignment. All other study personnel will be encouraged to remain blinded to the participant’s treatment assignment. Additional blinding procedure information will be in the PassItOn Blinding Procedure Document.

**Procedure:**

|  |  |  |
| --- | --- | --- |
| **Step** | **Action** | **Related Documents** |
| 1 | Receive plasma into inventory* Inspect unit
* CP will arrive with two hang tags:
* a red hang tag with the study ID #, and
* one stating “COVID 19 Convalescent Plasma”
* Enter “CCPL” as an antigen/antibody. This will translate to COVID-19 Convalescent Plasma
* Store CP in designated area of ≤ -18C freezer
* Place original ODR in managers door.

Note: If plasma has a decimal point in the volume round up to the next whole number mL. | Order Distribution Report (ODR)Receiving Blood Products into InventoryBlood Product Inspection PolicyVisual Inspection of Plasma ProductsSQ Blood Product EntryBlood Product Storage Policy |
| 2 | Research Coordinator will place paper order for an ABRH and send patient sample via tube station.  | Special Billing – RRR Clinical Research Order Form |
| 3 | Order ABRH in SQ using OE* On the RRR line, enter or scan **RG1121196**
 | SQ Order Entry Process |
| 4 | Perform patient testing. Notify research coordinator of blood group. |  |
| 5 | Patient is randomized by research coordinator. * If on plasma arm, the PI will place CPOE order for Plasma with comment “PassItOn”. Receive order in Sunquest. Enter RG1121196 under RRR account number in ORM.
* Verify group specific CP is available. Contact Research Coordinator if there is none. If outside the hours of 8a-5p Central and weekends, place a call to 615-200-7428 and ask if they would like us to use the Group A plasma (if available) or if they would like to ship type specific.
* Place a photocopy of the plasma order in the manager’s mailbox. Manager will add to study log.
 | SQ Order Entry Process |
| 8 | Bedside Staff:* When ready to transfuse, the bedside staff will release the transfuse order in Epic and the release will print in TSL.

TSL:* Thaw CP, preferentially using Helmer Quickthaw waterbath
* Perform Blood Component Prep using BCP
* Label check unit and apply new label
* Allocate thawed plasma to patient
* Contact Research Coordinator for pickup
* Issue unit to Research Coordinator having them sign the Blood Product Release Form
 | Blood Product Release form from Epic (BPR)Thawing Products Using the Helmer Quickthaw SystemThawing Products using the ARK Microwave Plasma DefrosterVisual inspection of Plasma ProductsSQ Preparation of Thawed PlasmaSQ Blood Label Check (BLC) and VerificationManual Label Verification FormSQ Blood Order ProcessingBlood Product Issue ProcessSQ Blood Product Issue |
| 9 | If transfusion reaction is suspected:* Verify bedside nurse has stopped the transfusion
* Contact LMR/Medical Director and inform them patient part of PassItOn and provide information to which arm the patient has been assigned.
* Placebo arm: LMR/Medical Director can inform Study Coordinator and bedside nurse they do not believe patient is having a transfusion reaction. Study coordinator will work with primary care team.
* Plasma arm: LMR/Medical Director will work with Study Coordinator and bedside nurse to send a transfusion reaction investigation (sample if necessary and form)
* Order transfusion reaction if requested using Order Entry. Add RG1121196 under RRR account number
 | Transfusion Reaction InvestigationSQ Order Entry Process |

**References:**

Technical Manual. Bethesda, MD: AABB Press, current edition

Standards for Blood Banks and Transfusion Services. Bethesda, MD: AABB Press, current edition

Passive Immunity Trial for Our Nation (PassItOn) Convalescent Plasma Study, Protocol V6.0