**Purpose:**

To provide instructions for ordering, receiving, storing, and selecting COVID-19 Convalescent plasma (CCP) 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 COVID-19 Convalescent Plasma Study.

**Policy:**

* Study patients are consented by the physician or principle investigator and require IND approval from the FDA prior to enrollment in the CCP protocol.
* Attending physician or principle investigator will contact TSL Medical Director with patient information and study approval.
* CCP components are stored at ≤ -18 C segregated from standard plasma units to prevent inadvertent use by non-study patients
* CCP components are ordered on an “as needed” basis from the blood supplier by HMC TSL staff upon receipt of order for CCP for the patient.
* Orders for CCP components are placed through ORCA, with the special instructions “COVID-19 Convalescent Plasma”.
* Each enrolled patient will be issued only one unit of CCP
* Transfusion reactions related to the transfusion of CCP will be reported to HMC TSL and worked up per standard policy in addition to reporting to the research coordinator and the blood supplier.

**Procedure notes and limitations:**

* CCP components are to be allocated and issued only to patients approved and enrolled in clinical study.
* Units not transfused to the intended participant will either be discarded or returned to blood supplier. Place unit in quarantine, report on QIM form, and notify TSL Manager.

**Principle**

CCP is a prospective, multi-center, trial being performed to determine the clinical benefits of the use of convalescent plasma in patients with diagnosis of COVID-19.

CCP components are collected from recovered patients who are otherwise eligible for blood donation and the units will be fully licensed. CCP components will be labeled with the following statement; “Convalescent Plasma; This product contains SARS-CoV2 antibodies measured using an investigational assay. CAUTION: New Drug-Limited by Federal (or US) lab to Investigational Use”. The CCP will be assigned by the blood supplier for a specific patient and will be ABO compatible.

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: This study is not blinded, the study coordinator and hospital/clinic care staff will be aware of the patient’s treatment with CCP.

**Procedure:**

|  |  |  |
| --- | --- | --- |
| **Step** | **Action** | **Related Documents** |
| 1 | Physician or principle investigator will place order in ORCA. |  |
| 2 | Receive plasma order through Order Receipt/Modify (ORM) | SQ Order Entry Process |
| 3 | Document the following on the COVID-19 Convalescent Plasma (CCP) Study Protocol Log   * Order date * Patient MRN * Patient Name * ABO of patient from HMC tested sample | COVID-19 Convalescent Plasma (CCP) Study Protocol Log |
| 4 | Place order for one unit of plasma in BloodHub and add a comment “Convalescent Plasma”.   * Fax a copy of the “Request for COVID-19 Convalescent Plasma” to BWNW IM. * If requested, fax a copy of the Mayo or other protocol approval letter   Note: If special request made by TSL Medical Director/research team for CCP from American Red Cross (ARC); contact them for order forms and instructions. | BloodHub Training Materials  BWNW Request for COVID-19 Convalescent Plasma Form |
| 5 | Contact courier service for pickup from BWNW IM |  |
| 6 | Receive plasma into inventory   * Inspect unit * CCP will arrive with a tie tag designated “Convalescent Plasma; This product contains SARS-CoV2 antibodies measured using an investigational assay. CAUTION: New Drug-Limited by Federal (or US) lab to Investigational Use”. If missing, contact supplier. * Enter “CCPL” as an antigen/antibody. This will translate to COVID-19 Convalescent Plasma * Document unit number and division on COVID-19 Study Log * Document Patient Code (if listed on ODR) * Store CCP in designated area of ≤ -18C freezer * Notify clinical team of product availability | Order Distribution Report (ODR)  Receiving Blood Products into Inventory  Blood Product Inspection Policy  Visual Inspection of Plasma Products  SQ Blood Product Entry  Blood Product Storage Policy  COVID-19 Convalescent Plasma Study Log |
| 7 | Clinical team will initiate transfuse task and release will print, Once printed:   * Thaw CCP * Perform Blood Component Prep using BCP * Label check unit and new label * Allocate thawed plasma to patient * Issue unit to floor | Blood Product Release form from ORCA (BPR)  Thawing Products Using the Helmer Quickthaw System  Thawing Products using the ARK Microwave Plasma Defroster |
| **Step** | **Action** | **Related Documents** |
| 7 (cont) |  | Visual inspection of Plasma Products  SQ Preparation of Thawed Plasma  SQ Blood Label Check (BLC) and Verification  Manual Label Verification Form  SQ Blood Order Processing  Blood Product Issue Process  SQ Blood Product Issue |
| 8 | After issue final, credit unit if provided by supplier at no cost. |  |

**References:**

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

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

Investigational COVID-19 Convalescent Plasma-Emergency INDs: FDA 04/04/2020

Investigational COVID-19 Convalescent Plasma Guidance for Industry: FDA April 2020