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|  | **COVID-19 Convalescent Plasma** BB.P.1063 | **Dept:** | 324311 |
| **Dept Name:** | Blood Bank |
| **Effective Date:** |  |
| **Revised Date:** |  |
| **Name & Title**: CLIA Laboratory Medical Director | **Contact:** | Julie H. Simmons/ Christina S Warren |
| **Signature:** | **Date:** |  |

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1. **General Protocol Statement:**
2. **Purpose:** Convalescent plasma is plasma collected from individuals who have recovered from a particular virus or bacteria. This is given to patients to boost their immunity with the antibodies present from the donor. COVID-19 convalescent plasma has not yet been approved for use by FDA, it is regulated as an investigational product.  This plasma would contain antibodies to Severe Acute Respiratory Syndrome CoronaVirus 2 or SARS-CoV-2 (the virus that causes COVID-19).

Since this is investigational each hospital must register to be able to use this plasma. WFBMC has registered with the Mayo Clinic’s EAP protocol. Each physician who will administer the plasma will also need to register along with the patient to be treated.

1. **Responsible Department/Scope:**

 i. Procedure owner/Implementer: Julie H. Simmons/ Christina S Warren

 ii. Procedure prepared by: Julie Jackson

 iii. Who performs procedure: Department staff/management

1. **Definitions:**

**WC:** Winston Campus

**BBMD:** Blood Bank Medical Director

**HPMC:** High Point Medical Center

**WFBMC:** Wake Forest Baptist Medical Center

**IRB:** Institutional Review Board- an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities.

1. **Sections**:
2. Registering to acquire convalescent plasma
3. Ordering convalescent plasma
4. Processing the plasma
5. **Protocol: I. Registering to acquire convalescent plasma**

1. Each campus within the WFBHC system must register separately with the EAP protocol administered by Mayo Clinic.
	1. To register go to:[https://uscovidplasma.org [uscovidplasma.org]](https://urldefense.proofpoint.com/v2/url?u=https-3A__uscovidplasma.org_&d=DwMFAw&c=yzGiX0CSJAqkDTmENO9LmP6KfPQitNABR9M66gsTb5w&r=OiIgMhAvh-nPRa4UFUbISo7Z3NKS8AmgJrT5q1Ks_2g&m=s2OD8HJe4Q8UROPvdQihBdrH_xypD2clTrfWV16KTKE&s=6ef8z1ORpZ3lZBceXRajxHEaINYosq5naFsq1W9SC5M&e=)
	2. Each site must register with the Mayo Clinic.
		1. The WC BBMD must be informed of registration.
	3. The WC BBMD will register WFBMC.
	4. The WC BBMD will be the contact point for all sites and orchestrate ordering for all sites.
2. WFBH must get approval by the WFBH IRB committee.
	1. The IRB# for the use of convalescent COVID-19 plasma: IRB00065201
3. Once the hospital has been registered with Mayo Clinic each physician/PI ordering convalescent plasma must also register.
	1. Each registered physician/PI must contact the WC BBMD.
4. Each participating patient must then be registered by their treating physician/PI.
	1. **Only patients 18 years or older (male or female) can receive convalescent plasma.**
	2. Each patient will be assigned a confirmation patient code that the physician must use to order plasma.
	3. The physician/PI will email the assigned patient code to the WC BBMD.
5. Once the hospital is registered the ARC will send a link to the WC BBMD for ordering the convalescent plasma from the American Red Cross.
	1. This will eventually be available in Connect/Bloodhub
6. Currently only 1 convalescent plasma is allowed per patient.

**Protocol: II. Ordering convalescent plasma**

1. Once a patient is registered the physician will contact the Winston Campus Blood Bank Medical Director with patient information.
	1. This includes High Point patients
2. **The BB Medical Director must approve all convalescent plasma orders.**
3. BB management or designee will add a special message in the patient’s PCW in SCC:



* 1. A patient cannot receive a unit of COVID convalescent plasma unless this is in the patient’s PCW. This indicates that the BBMD has approved the plasma.
	2. If an order or inquiry is received direct to the BB Medical Director.
	3. This comment can be removed once the patient is discharged.
1. The Blood Bank Medical Director will order 1 unit of the convalescent plasma with ARC.
	1. ABO compatible plasma must be requested.
		1. If the patient is group B or AB and compatible plasma is not available group A plasma may be requested with Medical Director’s approval.
	2. This cannot be ordered on line in ARC’s Connect (Bloodhub) at this time.
2. The patient must have an ABORh performed within the last year per BB protocol.
	1. See *Plasma; BB.CP.1032*
3. Once the plasma is ordered from ARC the physician will be informed of the availability.

**Protocol: III. Processing the plasma**

1. Once the plasma (frozen) arrives in the Blood Bank it will be placed on a specifically segregated shelf in the plasma freezer until ready to thaw.
	1. Freezer location: Shelf 2 of Freezer 5 – Convalescent plasma
	2. The plasma will be clearly labeled: COVID-19 Convalescent Plasma.
	3. “Hold” the unit to the patient in SCC.
	4. Call the floor to see if they are ready for the plasma to be thawed.
2. When ready to transfuse the physician/PI will order a **Prepare Convalescent Plasma** order and a **Transfuse** **Convalescent Plasma** order in Epic. This will print in the blood bank at the front desk where all add-on product orders print.
	1. If an order prints off and the patient does not have the special message COVID plasma ordered, contact the BB Medical Director or BB management.
	2. This can only be ordered in Epic on patients who are 18 years or older AND have COVID-19 as a diagnosis. If the physician is having trouble ordering it may be one of these 2 criteria is not met.
3. The plasma will be thawed per normal plasma procedure.
	1. See *Plasma; BB.CP.1032*
4. This plasma CANNOT be given to anyone unless they have been approved by the BB Medical Director and the “COVID plasma ordered” comment is in PCW.
5. For HPMC patients who need COVID plasma:
	1. The patient’s physician must contact the WC BB Medical Director for approval and WC BBMD will order the plasma.
	2. The plasma (frozen) will be delivered to WC BB.
		1. The plasma will not be received into SCC at WCBB.
		2. The plasma will be immediately shipped to HPMC BB via courier.
		3. Once received at HPMC the plasma will be received into SCC.
		4. HPMC will then process the plasma per their protocol.
		5. The physician will need to order in Epic a **Prepare Convalescent Plasma** order and a **Transfuse** **Convalescent Plasma** order
	3. WC BB management will work with ARC to transfer the product to the HPMC ARC account.
6. **Review/Revised/Implemented:**

 All protocols must be reviewed according to the Document Change Protocol.

 All new protocols that have major revisions must be signed by the CLIA Director.

 All reviewed protocols with minor revisions can be signed by the designated section Medical

 Director.

1. **Related Protocols:**

Plasma; BB.CP.1032

1. **References**: NA

1. **Attachments**: NA
2. **Revised/Reviewed Dates and Signatures:**

 See Document Change Control

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| Document Change Control |
| **Title: COVID-19 Convalescent Plasma** |
| Previous title: |
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| **Reviews: Record Date/Initials** |
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