

	COVID-19 Convalescent Plasma BB.P.1063.1	Dept:	324311
		Dept Name:	Blood Bank
		Effective Date:	Title 21
		Revised Date:	Title 21
Name & Title: CLIA Laboratory Medical Director		Contact:	Julie H. Simmons/ Christina S Warren
Signature: Refer to Title 21		Date:	Title 21

1. General Protocol Statement:

A. 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.

B. 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

C. 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.

D. Sections:

- I. Registering to acquire convalescent plasma
- II. Ordering convalescent plasma
- III. Processing the plasma

2. Protocol: I. Registering to acquire convalescent plasma

- 1.0 Each campus within the WFBHC system must register separately with the EAP protocol administered by Mayo Clinic.
 - 1.1 To register go to: <https://uscovidplasma.org> [uscovidplasma.org]
 - 1.2 Each site must register with the Mayo Clinic.
 - a. The WC BBMD must be informed of registration.
 - 1.3 The WC BBMD will register WFBMC.
 - 1.4 The WC BBMD will be the contact point for all sites and orchestrate ordering for all sites.
- 2.0 WFBH must get approval by the WFBH IRB committee.
 - 2.1 The IRB# for the use of convalescent COVID-19 plasma: IRB00065201
- 3.0 Once the hospital has been registered with Mayo Clinic each physician/PI ordering convalescent plasma must also register.
 - 3.1 Each registered physician/PI must contact the WC BBMD.
- 4.0 Each participating patient must then be registered by their treating physician/PI.
 - 4.1 **Only patients 18 years or older (male or female) can receive convalescent plasma.**
 - 4.2 Each patient will be assigned a confirmation patient code that the physician must use to order plasma.
 - 4.3 The physician/PI will email the assigned patient code to the WC BBMD.

Refer to Attachment 1: Convalescent Plasma Process for COVID Patients for Physicians
- 5.0 Once the patient is registered, the convalescent plasma can be ordered from the American Red Cross in Connect/Blood Hub.
 - 5.1 The following designated employees will be responsible for placing the orders in Blood Hub:
 - Education Coordinator
 - Management
 - Designated Charge Techs
 - BB LIS Tech
- 6.0 Currently only 1 convalescent plasma is allowed per patient.
- 7.0 The patients can be added to the list that is located on the freezer close to the convalescent freezer. The patient's name, MRN, blood group can be added. Once the plasma order arrives, note the date on the list. Whenever plasma is given to a patient, note on the list also. This will help keep track of what is coming and who is next in line.

Protocol: II. Ordering convalescent plasma

- 1.0 Once a patient is registered the physician will email [Blood Bank orders DL@wakehealth.edu](mailto:Blood_Bank_orders_DL@wakehealth.edu) with patient information.
 - 1.1 This includes High Point patients
- 2.0 **The BB Medical Director has approved convalescent plasma orders for registered patients.**
- 3.0 BB management or designees listed in Section I, will add a special message in the patient's PCW in SCC:

COVID Plasma ordered

- 3.1 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.
- 3.2 If an order or inquiry is received direct to the BB Medical Director.
- 3.3 This comment can be removed once the patient is discharged.
- 4.0 The Designated employees will order 1 unit of the convalescent plasma with ARC in Connect/Blood Hub.
 - 4.1 ABO compatible plasma must be requested.
 - a. 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.
 - 4.2 The order will be placed as a SERVICE ORDER (Convalescent Plasma for the treatment of COVID-19).
 - 4.3 This will be entered under 'New Order'.
 - a. The Order Type is Services.
 - b. The Delivery Type is 'Routine.'
 - c. The order is 'Convalescent Plasma for the treatment of COVID-19'.
 - d. The protocol is EAP and the Point of Contact Name is Dr. Fadeyi (use [Blood Bank orders DL@wakehealth.edu](mailto:Blood_Bank_orders_DL@wakehealth.edu) for contact email).
 - e. The patient's blood type should be selected.
 - f. The additional information provided is entered on each screen and the order is then submitted.
- 5.0 The patient must have an ABORh performed within the last year per BB protocol.
 - 5.1 See [Plasma; BB.CP.1032](#)
- 6.0 Once the plasma is received from ARC the physician will be informed of the availability.

Protocol: III. Processing the plasma

- 1.0 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.
 - 1.1 Freezer location: Shelf 2 of Freezer 5 – Convalescent plasma
 - 1.2 The plasma will be clearly labeled: COVID-19 Convalescent Plasma.
 - 1.3 “Hold” the unit to the patient in SCC.
 - 1.4 Call the floor to see if they are ready for the plasma to be thawed.
- 2.0 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.
 - 2.1 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.
 - 2.2 The physician may place the transfuse order when he placed the request for COVID plasma. These can be kept in Component Prep until a plasma is available to give. Always call and make sure that the product is still wanted.
 - 2.3 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.
- 3.0 The plasma will be thawed per normal plasma procedure.
 - 3.1 See [Plasma; BB.CP.1032](#)
- 4.0 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.
- 5.0 For HPMC patients who need COVID plasma:
 - 5.1 The patient’s physician must contact the WC BB Medical Director for approval and WC BBMD will order the plasma.
 - 5.2 The plasma (frozen) will be delivered to WC BB.
 - a. The plasma will not be received into SCC at WCBB.
 - b. The plasma will be immediately shipped to HPMC BB via courier.
 - c. Once received at HPMC the plasma will be received into SCC.
 - d. HPMC will then process the plasma per their protocol.
 - e. The physician will need to order in Epic a **Prepare Convalescent Plasma** order and a **Transfuse Convalescent Plasma** order
 - 5.3 WC BB management will work with ARC to transfer the product to the HPMC ARC account.

3. 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.

4. Related Protocols:

Plasma; BB.CP.1032

5. References: NA

6. Attachments:

Attachment 1: Convalescent Plasma Process for COVID Patients for Physicians

7. Revised/Reviewed Dates and Signatures:

Refer to archive history/Title21

Attachment 1: CONVALESCENT PLASMA PROCESS FOR COVID PATIENTS FOR PHYSICIANS

If you think your patient qualifies for convalescent plasma, FIRST page
Either Dr. Niyati Jakharia (P. 0357) or Dr. Rita Bakhru (P. 9614) for initial approval
(Check attached schedule for on call provider)



Once approved, obtain consent (Clearly mention the name of person you took consent from if LAR and relationship.

If taken over the phone, have 2nd physician witness)

Also, clearly write your name with your signature in the form

Consent form is available on the Mayo EAP site

<https://www.uscovidplasma.org/pdf/EAP%20CP%20English%20Consent%2020.00331200.pdf>

(Available in Spanish/Arabic too)

UPLOAD THE SIGNED CONSENT IN MEDIA TAB



Fill out the patient enrollment form on the Mayo EAP website

https://redcap2.mayo.edu/redcap/surveys/?s=R3DHR7X8N4&_ga=2.150517566.921492579.1588625495-555570272.1586633183

For local physician name, enter

Niyati Jakharia (njakhari@wakehealth.edu , Cell: 8565713571) OR Rita Bakhru (rbakhru@wakehealth.edu, Cell: 2032413996), whoever gave the initial approval

Also, select yes for research coordinator, enter name: Pinchinat Rosabell Onyango

Email: ponyango@wakehealth.edu, Phone: 3367164760



Send ABO testing. After filling the form, you will get EAP number, send an email to Blood_Bank_orders_DL@wakehealth.edu and cc to efadevi@wakehealth.edu (Dr. Emmanuel Fadeyi)

And Niyati/Rita to place the order for plasma

INCLUDE: patient's MRN, patient's name, Blood type and EAP number

Enter prepare convalescent plasma orders in Wake One



Blood bank will contact you when plasma is available

Once you obtain the plasma, please have the nurses fill out a short note for follow up of 4-hr post transfusion.

The smart phrase for that is .covidplasma4hr

PLEASE NOTE: IF YOU DECIDE NOT TO USE THE PLASMA OR PATIENT PASSES AWAY BEFORE YOU OBTAIN THE PLASMA, PLEASE REACH OUT TO DR. FADEYI AND CC EITHER NIYATI/RITA TO CANCEL THE ORDER