ਡਾਇਰੈਕਟੋਰੇਟ, ਮੈਡੀਕਲ ਸਿੱਖਿਆ ਅਤੇ ਖੋਜ, ਪੰਜਾਬ

(ਮੈਡੀਕਲ ਸਿੱਖਿਆ ਭਵਨ, ਸੈਕਟਰ-69, ਐਸ.ਏ.ਐਸ, ਮੁਹਾਲੀ-160069)

(ਫੋਨ ਨੰਬਰ : 0172-5287760, Email Id: - dir.mer@punjab.gov.in)

ਨੋਟੀਫਿਕੇਸਨ

ਨੰਬਰ : 5ਐਮ.ਈ.3-ਪੰ-2020/10976 ਮਿਤੀ : 1-8-2020

ਇਸ ਦਫਤਰ ਵਲੋਂ ਜਾਰੀ ਕੀਤੀ ਗਈ ਨੋਟੀਫਿਕੇਸਨ ਨੰ: 26/7/2020-ਪੰ-5ਐਮ.ਈ.3/10573 ਮਿਤੀ 26-7-2020 ਨੂੰ ਸ਼ੋਧ ਕਰਦੇ ਹੋਏ ਸਪੱਸਟ ਕੀਤਾ ਜਾਂਦਾ ਹੈ ਕਿ Convalescent Plasma ਨੂੰ ਕੋਵਿਡ-19 ਦੇ ਮਰੀਜਾਂ ਦੇ ਇਲਾਜ ਲਈ ਮੁਫਤ ਦਿੱਤਾ ਜਾਵੇਗਾ।

ਕੋਵਿਡ-19 ਦੇ ਮਰੀਜਾਂ ਲਈ Convalescent Plasma ਪ੍ਰਾਈਵੇਟ ਅਤੇ ਸਰਕਾਰੀ ਹਸਪਤਾਲਾਂ ਨੂੰ ਮੁਫਤ ਦੇਣ ਸਬੰਧੀ ਵਿਭਾਗ ਵਲੋਂ General Terms and Conditions (CCP-1) ਅਤੇ Process Flow (CCP-2) ਜਾਰੀ ਕੀਤੇ ਜਾਂਦੇ ਹਨ। ਇਨ੍ਹਾਂ ਦੇ ਆਧਾਰ ਤੇ Requisition Form (CCP-3), Patient detail Form (CCP-4) ਅਤੇ Patient Information and Consent Form (CCP-5) ਨਿਰਧਾਰਤ ਕੀਤੇ ਜਾਂਦੇ ਹਨ। ਇਸ ਤੋਂ ਇਲਾਵਾ ਸਬੰਧਤ ਹਸਪਤਾਲਾਂ ਵਲੋਂ ਮੰਗ ਭੇਜਣ ਲਈ ਇਕ ਨੋਡਲ ਅਫਸਰ ਤੈਨਾਤ ਕੀਤਾ ਜਾਵੇਗਾ, ਜਿਸ ਸਬੰਧੀ Authorisation Form (CCP-6) ਭਰਿਆ ਜਾਵੇਗਾ।

ਇਹ ਨੋਟੀਫਿਕੇਸਨ ਸਮੱਰਥ ਅਥਾਰਿਟੀ ਦੀ ਪ੍ਰਵਾਨਗੀ ਨਾਲ ਜਾਰੀ ਕੀਤੀ ਜਾਂਦੀ ਹੈ।

Aunish Kumar

ਡਾਇਰੈਕਟਰ, ਮੈਡੀਕਲ ਸਿੱਖਿਆ ਅਤੇ ਖੋਜ, ਪੰਜਾਬ

ਪਿੱਠ ਅੰਕਣ ਨੰਬਰ: 5ਐਮ.ਈ.3-ਪੰ-2020/10977 ਮਿਤੀ : **1-8-2020**

ਉਤਾਰਾ ਕੰਟਰੋਲਰ, ਛਪਾਈ ਅਤੇ ਸਮੱਗਰੀ ਵਿਭਾਗ, ਪੰਜਾਬ ਨੂੰ ਪੰਜਾਬ ਸਰਕਾਰ ਦੇ ਗਜਟ (ਆਰਡਨਰੀ) ਵਿੱਚ ਛੱਪਣ ਲਈ ਭੇਜ ਕੇ ਬੇਨਤੀ ਕੀਤੀ ਜਾਂਦੀ ਹੈ ਕਿ ਇਸ ਦੀਆਂ 25-25 ਕਾਪੀਆਂ ਰਿਕਾਰਡ ਹਿੱਤ ਇਸ ਵਿਭਾਗ ਨੂੰ ਭੇਜੀਆਂ ਜਾਣ ।

Aunish Kumar

ਡਾਇਰੈਕਟਰ, ਮੈਡੀਕਲ ਸਿੱਖਿਆ ਅਤੇ ਖੋਜ, ਪੰਜਾਬ

ਪਿੱਠ ਅੰਕਣ ਨੰਬਰ: 5ਐਮ.ਈ.3-ਪੰ-2020/10978-10991 ਮਿਤੀ : **1-8-2020**

ਉਪਰੋਕਤ ਦਾ ਇੱਕ ਉਤਾਰਾ ਹੇਠ ਲਿਖਿਆਂ ਨੂੰ ਇਸ ਦਫਤਰ ਦੇ ਪੱਤਰ ਪਿੱਠ ਅੰਕਣ ਨੰ: 26/7/2020-ਪੰ-5ਐਮ.ਈ.3/10575-10588 ਦੇ ਹਵਾਲੇ ਸੂਚਨਾਂ/ਅਗਲੇਰੀ ਕਾਰਵਾਈ ਹਿੱਤ ਭੇਜਿਆ ਜਾਂਦਾ ਹੈ:-

i) ਮਹਾਂਲੇਖਾਕਾਰ (ਆਡਿਟ), ਪੰਜਾਬ, ਚੰਡੀਗੜ੍ਹ ।
ii) ਮਹਾਂਲੇਖਾਕਾਰ (ਲੇਖਾ ਅਤੇ ਹੱਕਦਾਰੀ), ਪੰਜਾਬ, ਚੰਡੀਗੜ੍ਹ ।
iii) ਪ੍ਰਮੁੱਖ ਸਕੱਤਰ, ਪੰਜਾਬ ਸਰਕਾਰ, ਮੈਡੀਕਲ ਸਿੱਖਿਆ ਅਤੇ ਖੋਜ ਵਿਭਾਗ, ਚੰਡੀਗੜ੍ਹ ।
iv) ਪ੍ਰਮੁੱਖ ਸਕੱਤਰ, ਪੰਜਾਬ ਸਰਕਾਰ, ਵਿੱਤ ਵਿਭਾਗ ।
v) ਡਾਇਰੈਕਟਰ, ਸਿਹਤ ਤੇ ਪਰਿਵਾਰ ਭਲਾਈ ਵਿਭਾਗ, ਪੰਜਾਬ, ਚੰਡੀਗੜ੍ਹ ।
vi) ਡਾਇਰੈਕਟਰ, ਵੈਲਫੇਅਰ ਆਫ ਸ਼ਡਿਊਲਡ ਕਾਸਟਸ ਐਂਡ ਬੈਕਵਰਡ ਕਲਾਸਿਸ, ਪੰਜਾਬ, ਚੰਡੀਗੜ੍ਹ ।
vii) ਰਜਿਸਟਰਾਰ, ਬਾਬਾ ਫਰੀਦ ਯੂਨੀਵਰਸਿਟੀ ਆਫ ਹੈਲਥ ਸਾਇੰਸਜ, ਫਰੀਦਕੋਟ ।
viii) ਪ੍ਰਿੰਸੀਪਲ, ਸਰਕਾਰੀ ਮੈਡੀਕਲ ਕਾਲਜ, ਪਟਿਆਲਾ/ਅੰਮ੍ਰਿਤਸਰ ।
ix) ਪ੍ਰਿੰਸੀਪਲ, ਸਰਕਾਰੀ ਡੈਂਟਲ ਕਾਲਜ ਅਤੇ ਹਸਪਤਾਲ, ਪਟਿਆਲਾ/ਅੰਮ੍ਰਿਤਸਰ ।
x) ਪ੍ਰਿੰਸੀਪਲ, ਗੁਰੂ ਗੋਬਿੰਦ ਸਿੰਘ ਮੈਡੀਕਲ ਕਾਲਜ ਅਤੇ ਹਸਪਤਾਲ, ਫਰੀਦਕੋਟ ।
xi) ਨਿੱਜੀ ਸਕੱਤਰ/ਐੱਮ.ਈ.ਆਰ.ਐੱਮ.।
xii) ਸਕੱਤਰ/ਪੀ.ਐੱਸ.ਐੱਮ.ਈ.ਆਰ.।
xiii) ਸ.ਸ.ਸ/ਯੂ.ਐੱਸ.ਐੱਮ.ਈ.ਆਰ.।
xiv) ਰਿਕਾਰਡਰ ਸਿਹਤ-3 ਸ਼ਾਖਾ ।

Aunish Kumar

ਡਾਇਰੈਕਟਰ, ਮੈਡੀਕਲ ਸਿੱਖਿਆ ਅਤੇ ਖੋਜ, ਪੰਜਾਬ

GOVERNMENT OF PUNJAB
DIRECTORATE, MEDICAL EDUCATION & RESEARCH, PUNJAB
SAS NAGAR, MOHALI

General Terms and Conditions for Issuance of Convalescent Plasma:

1. Each COVID-19 treatment centre/ hospital, whether in Govt. or Private, shall notify a nodal officer to co-ordinate for requisitioning of COVID-19 convalescent plasma.
2. Plasma would be issued to government and private hospitals of Punjab and prioritized depending upon the clinical urgency.
3. The convalescent plasma would be issued to the concerned hospital with the understanding that there would be no commercial intent or profit motive in its usage. Further the hospital will certify that they are not charging the patient, higher than the rates prescribed by the Punjab Govt for COVID treatment.
4. COVID-19 convalescent plasma will be issued only on the request/prescription of the treating physician; no patient attendant shall solicit plasma for their patient without valid prescription.
5. The requisition of plasma along with blood sample for grouping would be properly checked by the physician and the concerned hospital, and it would be their responsibility to check the plasma received from the plasma bank before usage in the patient.
6. It shall be the responsibility of the treating physician /Nodal officer to: -
   a. Assure that plasma is requisitioned and to be utilized as per the DCGI/ ICMR guidelines (Version 4, 27.6.2020, MoHFW notification, or as updated from time to time)
   b. Requisition form (Form–1) and blood sample is sent as per legal requirements to plasma bank.
   c. All information requested on the patient clinical details (Form–2) is filled and duly signed by the treating physician and countersigned by the nodal officer of the concerned hospital
   d. Follow-up and outcome are to be reported to nodal officer plasma bank on a regular basis.
7. The COVID-19 convalescent plasma shall be used only for off label use on a compassionate basis as per prevailing MoHFW, GoI guidelines and not as a part of any clinical trial. (Off-label use means, physicians can use an approved therapy for an as yet unapproved indication).
8. Outcomes of use of this COVID-19 convalescent plasma will not be used for any academic presentation or publication without prior permission of the **Director, Medical Education & Research, SAS Nagar, Mohali**
9. The physician and the concerned hospital requisitioning the plasma would be entirely responsible for the correct selection of the patients, plasma infusion, monitoring of the patients, management of adverse events and the outcomes, including mortality.
10. Every hospital would keep a record of all the patients, as per the guidelines set for the blood banks.
11. If the above conditions are not met, COVID-19 convalescent plasma will not be issued to the defaulting hospital.
12. Neither the **Director, Medical Education & Research, SAS Nagar, Mohali** nor Plasma Bank or GMC's would be directly or indirectly, legally and/or financially liable for outcomes of the off-label use of plasma therapy.

Avnish Kumar

PROCESS FLOW FOR CONVALESCENT PLASMA USE IN PUNJAB

1. Patients who meet the following criteria can be given plasma therapy. The patient is admitted in a COVID approved Hospital and meets any of the following inclusion criteria:
    a. ICMR definition:
        i. Patients admitted with RT-PCR confirmed COVID-19 illness
        ii. Either of these 2
            1. PaO2/ FiO2: 200-300
            2. Respiratory Rate > 24/min and SaO2 < 93% on room air
    b. MOHFW definition:
        i. Adolescent or adult with presence of clinical features of dyspnoea and or hypoxia, fever, cough, including SpO2 <94% (range 90-94%) on room air, Respiratory Rate more or equal to 24 per minute/
        ii. Child with presence of clinical features of dyspnoea and or hypoxia, fever, cough, including SpO2<94% (range 90-94%) on room air, Respiratory Rate more or equal to 24 per minute.
2. Patient certified to be not in exclusion criteria
    a. Pregnant women
    b. Breastfeeding women
    c. Known hypersensitivity to blood products
    d. Receipt of pooled immunoglobulin in last 30 days
    e. Critically ill patients:
        i. P/F ratio <200 (moderate - severe ARDS)
        ii. Shock (Requiring Vasopressor to maintain a MAP >= 65mmHg or MAP below 65)
    f. Participating in any other clinical trial
    g. Clinical status precluding infusion of blood products
3. Special Requisition form filled
4. Online form filled and sent to the Convalescent plasma committee
5. Committee approval
6. The requisitioner reaches the Plasma Bank with the special requisition form (*patient sample for grouping*)
7. Plasma Issued
8. First dose transfused to patient
9. Feedback sent to the online form (format under preparation)
10. Second dose transfused to the patient
11. Feedback sent to the online form (format under preparation)
12. Follow- up at 48 hours (format under preparation)
13. Final outcome (discharge /death etc)

Avnish Kumar

Plasma Bank, _____

Request Form for COVID 19 Convalescent Plasma ("Off-label" use)

Patient's Name:- _____Hospital Regd. No_____ Age/Sex: _____
Father's / Husband's Name:- _____Address:_____
Name of the Hospital _____ Ward/Room (Bed) No. _____
Blood Group: _____Clinical Diagnosis:_____
Doctor in Charge: _____
Indication for transfusion:_____
No. of Units Required_____ Date: _____ Time: _____

Previous History of
Transfusion: Yes □ No □ If Yes, specify: _____
Transfusion Reaction: Yes □ No □ If Yes, specify: _____
Pregnancies, HDNB, Still Birth, miscarriage: Yes □ No □
IgA (Immunoglobulin A) deficiency syndrome or allergy to immunoglobulins: Yes □ No □

Pre-Transfusion Hematological values
Hb _____ PT_____ APTT _____ Platelet Count_____

Sample collected by Name: _____ Sign: _____

Certified that I have checked the labels & verified patient's data

Sign of Doctor:_____ Time: _____
Name of Doctor:_____ Date: _____
Contact Number: _____

Patient/Relatives Consent
I am ready to get COVID-19 Convalescent Plasma ("Off label" use) for me or my relative at my own risk and the risk has been explained to me. The consent form has been seen and signed by me.

Signature of Patient/Relative: _____ Date: _____
Name of Patient/Relative: _____ Time: _____

Doctor's Consent for Transfusion
I am ready to give COVID-19 Convalescent Plasma transfusion ("Off label" use) to my patient. The patient information sheet and informed consent form have been duly signed and placed in the patient case file and the risks of blood transfusion including Transfusion Transmitted Infections have been explained to the patient or relatives.

Signature of Doctor: _____ Date: _____
Name of Doctor: _____ Time: _____

Nodal Officer's Declaration
Certified that there would be no commercial intent or profit motive in the use of convalescent plasma. Certified that our hospital is not charging the patient, higher than the rates prescribed by the Punjab Govt for COVID treatment.

Signature of Nodal Officer: _____ Date: _____
Name of Nodal Officer: _____ Time: _____

INSTRUCTIONS
1. 5 ml patient's blood should be sent in a properly labelled EDTA tube along with requisition form.
2. The requisition must be complete in all respect and signed. Details should be same both on the requisition form and the label of the blood sample.
3. Requisition forms are accepted 24x7 at Reception Desk at Blood Bank/Plasma Bank.
4. Convalescent Plasma must be taken when required for definite use.
5. Patient should be closely monitored for adverse effects of plasma and appropriate intervention should be instituted, if needed.
6. CCP therapy may be given along with other therapies like Remdesivir, Tocilizumab, etc.
7. Patient should be monitored for improvement/deterioration after CCP therapy.

Avnish Kumar

CCP-4

Plasma Bank, _____

PATIENT CLINICAL DETAILS
(To be filled by Treating/Requisitioning Hospital)

Name of Hospital: _____
Patient Name: _____Registration No.: _____
Age/ Sex: _____Phone no: _____ Address: _____
Date of Testing Positive for SARS CoV 2 (RT-PCR):_____

Present complaints	**YES**	**NO**	**IF YES, DURATION**
1. Fever			
2. Dry Cough			
3. Breathlessness			
4. Sputum production, if any			
5. Pain in abdomen			
6. Nausea			
7. Anorexia			
8. Diarrhoea			
9. Myalgia			
10. Fatigue			
11. Loss of smell			
12. Loss of taste			
13. Shock			
14. Any other:			

Patient Parameters	
1. Respiratory Rate	
2. Oxygen saturation level (SpO2 on room air)	
3.Partial pressure of oxygen (PaO2)/oxygen concentration (FiO2)	
4. Lung infiltrates	Present /Absent
5. Supplemental Oxygen	Yes / No
6. On Mechanical Ventilation	Yes / No
7. Any other specific information	

Sign. of Treating Consultant :-_____
Name:-_____
Designation :- _____
Contact Number:- _____

Countersigned by Nodal officer _____

Avnish Kumar

Patient Information Sheet

Patient Unique ID: _____ **Date:_____**

As You/Your family member is being considered to receive an **OFF-LABEL drug COVID-19 Convalescent Plasma (CCP),** as investigational therapy for treatment. This document will explain you about the use/rationale of this CCP therapy, possible risks, benefits, and alternatives. It is requested that you read this information carefully and in case of any doubt you are free to ask questions to our team members.

Rationale to use CCP therapy:

The novel corona virus disease (COVID-19), which began in Wuhan, China, in December 2019, has been declared to be a pandemic by the World Health Organization (WHO). This is caused by the severe acute respiratory syndrome corona virus 2 (SARS-CoV-2), which infected millions of peoples and thousands of deaths globally and in India.

The clinical manifestations of COVID-19 disease range from fever, cough, fatigue, sore throat, shortness of breath and less common symptoms such as headache, nausea and diarrhea. The most common complications are sepsis, respiratory failure, acute respiratory distress syndrome (ARDS), cardiac injury and acute kidney injury. Currently, there are no approved treatments for COVID-19 disease. The management plan is supportive care with supplemental oxygen and mechanical ventilation. Multiple trials are being done across the globe to assess the efficacy of various treatment strategies including some medicines/ drugs.

Some previous studies reported improvement in critically ill COVID-19 patients with ARDS after infusion of CCP that containing neutralizing antibodies against SARS-CoV-2 virus. Historically, it has been used in previous viral outbreaks like SARS (2002-2004), and MERS (2012-2014) with some benefit. Considering the lack of efficacious treatments for COVID 19 and on the basis of previous studies results, US FDA and Indian regulatory bodies have approved CCP therapy for COVID-19 patients as an off-label drug.

Decision to receive CCP therapy:

This is an entirely voluntary decision of you/your family members to receive CCP therapy. At any time, you can refuse to take this therapy without giving any reason. Your refusal to take this therapy will not involve any penalty or loss of benefits which you and your family member are/is otherwise entitled to.

Eligibility to receive CCP therapy:

You or your family member is eligible to receive CCP therapy if the following criteria are met:

Indian Council of Medical Research (ICMR) Criteria:

1. You/your relative should be confirmed RT-PCR positive for COVID-19 disease &
2. The PaO2/ FiO2 or respiratory rate of your/yours' relative should be 200-300 or > 24/min, respectively
   AND
   The SpO2 of your/yours' relative should be < 93% on room air.

Ministry of Health and Family Welfare (MOHFW) Criteria:

1. You/your relative should have presence of clinical features of dyspnea and or hypoxia, fever, and cough
   AND
   The SpO2 of your/yours' relative should be <94% (range 90-94%) on room air &
2. You/your relative should have respiratory rate more or equal to 24/minute.

Possible benefits of the therapy:

CCP therapy might provide some improvement in moderately ill patients. After receiving CCP therapy some patients showed improvement in respiratory functions, they did not require supplemental oxygen or mechanical ventilation or such requirement decreased. Their total length of intensive care unit (ICU) and hospital stay also reduced.

Possible risks of this therapy:

Previous studies showed that CCP therapy is safe and there is no additional risk other than the risk associated with any other plasma transfusion (e.g. very small risk of infections like hepatitis, HIV, etc.). After transfusion of plasma there might be chances of few transfusion reactions like allergic/anaphylactic reactions, febrile non-hemolytic transfusion reactions (FNHTR), hemolytic transfusion reactions (HTR), transfusion associated circulatory overload (TACO) and transfusion related acute lung injury (TRALI) etc. Most of these reactions are dependent on the recipients' condition and his/her immunity.

Alternative treatment strategies:

The decision to receive CCP therapy is entirely voluntary, you can consult with your clinicians for the availability of alternative treatments.

Avinash Kumar

Informed Consent Form

S. No.	Particulars
1.	I/we have been explained in my own language and I have read the information sheet regarding the need for CCP in me /or my patient as an off-label indication due to the clinical condition of the patient.
2.	I have also been explained about the risks, alternatives and benefits of using CCP in a language that I understand.
3.	I have had the opportunity to ask my queries related to the CCP Therapy.
4.	I understand that, risks of CCP are similar to those with the use of any blood/ blood component, viz (but not limited to) allergic reaction, haemolytic reaction, febrile reaction and in extreme conditions death due to any or all of these reactions.
5.	I also understand that the CCP therapy may not result in the desired benefit as it is still under investigational drug, viz improvement in the patient's health/ clinical condition.
7.	I also understand that the blood center will provide me the best possible and compatible convalescent plasma unit for the transfusion. In the absence of commercially available validated kits for quantitative estimation of antibodies to measure plasma IgG titre, I am willing to accept the product with a qualitative test and I will not hold the blood center/hospital responsible if this product fails to produce the desired result.
6.	I / we understand that the final decision to transfuse CCP to me/my relative has been taken by me and the treating clinical team. I will not hold the blood centre, hospital or treating physician responsible directly or indirectly, legally and/or financially for outcomes of the off-label use of plasma therapy.
7.	I know that I or my family member have the liberty of refuse to take this treatment at any time, without giving assigning any reason, without his/her medical care or legal rights being affected.
8.	I give my consent for the use of CCP therapy on me/my patient as an off-label indication.

Signature (or Thumb impression) of the Patient or Patient's relative: _____

Signatory's Name: _____**Relationship with patient:** _____

Witness name and signature: _____

Date: _____

Note: Considering difficult access to the patient's isolation ward/ICU, the consent may be signed by patient's relative {legally authorized representative (LAR)}. A copy of this consent form should be sent to blood center along with the requisition form

Avnish Kumar

CCP-6

PLASMA BANK, _____

Form for **One Time Nomination** of Nodal Officer by MS/DMS of Hospital

For Requisitioning COVID Convalescent Plasma (CCP) From Plasma Bank, _____

1	Name of hospital proposing to use Convalescent plasma for COVID patients	:	
2	Address	:	
3	Name of Medical Superintendent/ Operational Head	:	
4	Name and Designation of Nodal Officer designated for requisition of CCP	:	
5	Contact Number:	:	
6	Agreement to Terms and Conditions	:	

Terms and Conditions of Issue of Convalescent Plasma

1. I / we hereby notify the above-mentioned ***nodal officer*** to co-ordinate and requisition of COVID-19 convalescent plasma from Plasma Bank.
2. I / We agree that COVID-19 convalescent plasma will be issued only on the request/prescription of the treating physician; no patient attendant shall solicit plasma for their patient without valid prescription.
3. I / We agree that the requisition of plasma along with blood sample for grouping and matching would be checked and verified by the physician, and it would be their responsibility to check, the plasma received from the plasma bank, before usage in the patient.
4. I / We agree that the ICMR guidelines (Version 4, 27.06.2020 or as updated from time to time) and DCGI Guidelines (01.07.2020 or as updated from time to time) or prevailing guidelines in this regard shall be followed.
5. I / We agree that it shall be the responsibility of the treating physician /Nodal officer to: -
   a) Requisition form and blood sample is sent as per legal requirements to Plasma Bank.
   b) All information requested on the patient information sheet is filled and duly signed by the treating physician and countersigned by the nodal officer of the concerned hospital.
   c) Transfusion follow-up and treatment outcome is reported to nodal officer Plasma Bank in the designated format as early as possible.
6. I / We agree that the COVID-19 convalescent plasma shall be used only for ***off label*** use on compassionate basis as per ICMR guidelines (Version 4, 27.6.2020 or as updated from time to time) and DCGI Guidelines (01.07.2020 or as updated from time to time) and not as a part of any clinical trial. (Off-label use means, physicians can use an approved therapy for an as yet unapproved indication).
7. I / We agree that outcomes of use of this COVID-19 convalescent plasma will not be used for any academic presentation or publication without prior permission of institutional head of plasma bank.
8. I / We shall be entirely responsible for the correct selection of the patients, plasma infusion, monitoring of the patients, management of adverse events and the outcomes, including mortality.
9. I / We would keep a record of all the patients, as per the guidelines set for the blood banks.
10. Plasma Bank, _____ would not be directly or indirectly, legally and/or financially liable for outcomes of the off-label use of plasma therapy.

Nodal Officer:
Signature:
Name:
Designation:
Contact number:
E-mail:

I,_____, Medical Superintendent/Operational Head, _____ Hospital do hereby declare that I have read and understood the conditions mentioned above and agree to abide by the same for the purpose of Convalescent Plasma Use in my hospital. Further, _____ is hereby authorized as the Nodal Officer from this Hospital to requisition CCP.

Signature:
Name:
Designation:
Contact Number:
Email:

Avnish Kumar