

COVID-19 Convalescent Plasma (CCP) Therapy (Off Label)
Patient Information Sheet & Consent form

Patient Name:	Age/Gender :	Blood Group:
IP number:	Ward:	Hospital:
Name of Doctor:	Doctor's Mobile No.	Date:

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

1. Rationale to use CCP therapy:

The novel corona virus disease (COVID-19), which began in Wuhan, China, in December 2019, has been declared a pandemic by the World Health Organization (WHO). This is caused by Severe Acute Respiratory Syndrome Corona Virus-2 (SARS-CoV-2), which has infected millions of people and caused lakhs of deaths globally and in India. The clinical manifestations of COVID-19 disease range from fever, cough, fatigue, sore throat, shortness of breath to less common symptoms such as headache, nausea and diarrhoea. 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 contained 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, US FDA and Indian regulatory bodies have approved CCP therapy for COVID-19 patients as an off-label drug.

2. 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.

3. Eligibility to receive CCP therapy :

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

A. Indian Council of Medical Research (ICMR) Criteria:

- i. You/your relative should be confirmed RT-PCR positive for COVID-19 disease.
- ii. The PaO₂/ FiO₂ or respiratory rate of you/your relative should be 200-300 or > 24/min, respectively.
- iii. The SpO₂ of you/your relative should be < 93% on room air.

B. Ministry of Health and Family Welfare (MOHFW) Criteria:

- i. You/your relative should be confirmed RT-PCR positive for COVID-19 disease.
- ii. You/your relative should have presence of clinical features of dyspnea and or hypoxia, fever, and cough .
- iii. The SpO₂ of you/your relative should be <94% (range 90-94%) on room air.
- iv. You/your relative should have respiratory rate more or equal to 24/minute.

4. 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, and decreased requirement of supplemental oxygen or mechanical ventilation was observed. Their total length of intensive care unit (ICU) and hospital stay also reduced.

5. 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 therapy. After transfusion of plasma there might be the chances of a few transfusion reactions like allergic/anaphylactic reactions, febrile non-hemolytic transfusion reactions (FNHTR), hemolytic transfusion reactions (HTR), transfusion associated circulatory overload (TACO) transfusion related acute lung injury (TRALI) and the risk of transfusion transmitted infection etc. Most of these reactions are dependent on the recipient's condition and his/her immunity.

6. Alternative treatment strategies:

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

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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 therapy 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 the risks of CCP are similar to those with the use of any blood/ blood components, including 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 an investigational drug and therefore may not show improvement in the patient's health/ clinical condition.
6	I also understand that the blood centre will provide me with 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 CCP with a qualitative test and I will not hold the blood centre/hospital responsible if this product fails to produce the desired result.
7	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 CCP therapy.
8	I know that I or my family member have been given the liberty to refuse to take this treatment at any time, without giving any reason without his/her medical care and legal rights being affected.
9	I, hereby, 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:

<i>To be filled by Doctor/Designee only</i>
Signing my name below means I have explained this PIS ICF for Off label use of CCP to the recipient/recipient's relative and answered his/her questions to the best of my ability.
Signature of the Doctor/Designee: _____
Name of the Doctor/Designee: _____
Affiliation of Doctor/Designee: _____
Date:

Note:

- i. 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, Mahatma Gandhi Medical College and Hospital, Jaipur along with the Blood Requisition Form(MGH/BB/F/REQ/32).
- ii. Please send screen shot or scanned copy of this PIS cum ICF form (MGH/BB/CCP/PISICF/PT/197) after filling all the details of recipient on Whatsapp no 9602779900 or 9829332844 or mail on covidplasmamgh@gmail.com