

## Appendix 1

### Data collection sheet of moderate COVID-19 patient

Name:			Hospital: File		Contact:	
CID:			Age: Sex:		Nationality:	
Risk factors:	DM	HTN	Bronchial asthma	Smoker	Others:	
Medications:						

Criteria for patient enrollment for CP COVID 19	
>18 years of age	
Confirmed lab COVID19	
Informed consent	
Dyspnoea	
Oxygen sat =>90%	

Date of PCR		LDH		Ferritin		CRP	
Admission Date:	CBC	WBC	HB	PLT	LY	DD	
	CXR	○ Normal ○ Abnormal				PT/APTT	

CCP transfusion					
LY	LDH	CRP	DD	PT/APTT	Ferritin
Date	Volume	CCP unit no.	Premedication		Reaction
1 <sup>st</sup>					Yes No
2 <sup>nd</sup>					Yes No

\*2<sup>nd</sup> dose can be given within 12 hrs

Observation post CCP infusion:												
Days	RR	Sp O <sub>2</sub> %	Mode of Vent.	O <sub>2</sub> supply in L or FiO <sub>2</sub> %		CXR	LDH	CRP	LY	DD	PT/APTT	Ferritin
D1				RA	L							
D3				RA	L							
D7				RA	L							
D11				RA	L							
D14				RA	L							
D17				RA	L							
D21				RA	L							
<b>CT chest if completed</b>												
Date:			Findings:									
Discharge Date:												

Doctor's name:

Doctor's signature:

## Appendix 2

### Data collection sheet of severe COVID-19 patient

Name:			Hospital:			File No:			
CID:			Age:		Sex:		Nationality:		
Risk factors:	DM	HTN	Bronchial asthma	Smoking	Others:				
Medications:									

<b>&gt;18 years of age</b>	
<b>Confirmed lab COVID19</b>	
<b>Informed consent</b>	
<b>Dyspnoea RR&gt;30 or</b>	
<b>Oxygen sat = &lt;90%</b>	

<b>Date of diagnosis by PCR</b>		Ferritin		<b>CRP</b>	
<b>Admission Date:</b>	<b>CBC</b>	WBC	HB	PLT	<b>DD</b>
	<b>CXR</b>	<input type="radio"/> Normal <input type="radio"/> Abnormal			<b>PT/APTT</b>

CCP transfusion					
Ly	CRP	LDH	DD	Ferritin	PT/APTT
Date	Volume	CCP unit no.	Premedication	Reaction	
1 <sup>st</sup>				Yes	No
2 <sup>nd</sup>				Yes	No

\*2<sup>nd</sup> dose CP can be given within 12 hrs.

Observation post CCP infusion:											
Days	R R	SpO <sub>2</sub> %	Mode of Vent.	O <sub>2</sub> supply in L or FiO <sub>2</sub> %		CX R	CR P	L Y	DD	PT/AP TT	Ferritin
D1				RA	L						
D3				RA	L						
D7				RA	L						
D11				RA	L						
D14				RA	L						
D17				RA	L						
D21				RA	L						
<b>CT chest if completed</b>											
<b>Date:</b>		<b>Findings:</b>									
<b>Date of transfer to ward:</b>											

Doctor's name:

Doctor's signature:

## Appendix 3

### PATIENT CONSENT AND PRIVACY AUTHORIZATION FORM FOR ABOVE 21 YEARS

**Title: COVID-19 Convalescent Plasma Treatment in SARS-CoV-2 Infected Patients:**

#### **Multicenter Interventional Study**

Please read this information carefully. It tells you important things about this research for use of the investigational product, Convalescent Plasma, for patients with COVID-19. A member of the clinical staff will talk to you about taking part in this research. If you have questions at any time, please ask us. Feel free to discuss the research with your family, friends, and healthcare provider before you make your decision. **NOTE:** If you are a family member or legally authorized representative signing this consent form for someone else, “you” in the consent form refers to the patient with COVID-19.

If you decide to take part in this research, you will sign this consent form to show that you want to take part. We will give you a copy of this form to keep. A copy of this form will be put in your medical record.

#### **If you have any questions regarding the following:**

- Procedures
- Any concerns or complaints
- Withdrawing from the research
- Rights of a research participant
- Any research-related concerns.
- Use of your Health Information

You can contact the principal investigator email: [salsharidah@moh.gov.kw](mailto:salsharidah@moh.gov.kw)

#### **Why are you being asked to take part in this research?**

You have been diagnosed with disease caused by the SARS-CoV-2 also known as coronavirus disease 2019 (COVID-19). SARS-CoV-2 is transmitted in a manner similar to influenza and other respiratory virus and has been associated with cough, fever, and shortness of breath, and in more severe cases, failure of the ability to breath, or even death. Currently, we don't have any approved medicines or vaccines to treat or prevent COVID-19.

People who recover from COVID-19 do so, at least in part, because their blood contains substances called antibodies, which are able of fighting the virus that causes the illness. It turns out that for some other diseases caused by respiratory viruses, giving people the liquid portion of blood, called plasma, obtained from those who have recovered from the virus, leads to more rapid improvement of the disease. We think that patients with COVID-19 may improve faster if they receive plasma from those who have recovered from COVID-19, because it may have the ability to fight the virus that causes COVID-19.

We are asking you to consider receiving plasma from someone who has recovered from COVID-19. Their plasma will have substances that could improve your chances of recovery.

We do not know if this treatment will or will not help you, and we don't know if it will have any harmful effects either, but this is one of the only treatments that we have at present, but you need to know that it has not yet been proven to work. Because we do not have any other treatment option at present, if you are willing, we would like to try this treatment out, and learn from the testing.

Because this therapy has not yet been tested, and you want to try this new therapy, we would like to learn as much as possible about its effects. We will therefore record some information about your response to the treatment, such as how long you needed to stay in the hospital or needed help with breathing.

### **What will happen to you while you are in this research?**

- You will be given plasma, the liquid portion of the blood, from a person who has recovered from COVID-19 that is compatible with your blood type. It will be given into one of your veins, using a sterile single use needle, and will be given over the course of about one to two hours. About 200-500 mL of plasma will be given in this infusion.

**What are the possible risks or discomforts from being in this research?** Blood and plasma have been used for many other conditions, and in general are very safe. Although the risk of contracting COVID-19 infection from receiving the treatment has not been formally tested yet, we believe that it would be very low because the donor has fully recovered from the infection. Transfusion also carries the risk of adverse reactions such as allergic reactions, transfusion-associated circulatory overload or lung damage with profound breathing difficulty, and transmission of infections including HIV and Hepatitis B and C; although the risk of these infections is very low, as only screened and compatible blood is used for transfusion.

**Can I change my mind after I say “Yes”?** Taking part in this research is voluntary. You can change your mind at any time. If you wish to stop the treatment, just tell your doctor. Your decision will not stop you from getting the usual care that all patients receive at this centre.

### **What are the possible benefits from being in this research?**

We do not know if convalescent plasma will be an effective treatment for COVID-19, and you might not experience any benefit. However, we believe that this treatment might be effective in improving the likelihood of you recovering from the disease.

**Do you have other choices?** You can choose to get this treatment or not. Your choice will not affect the care that you are receiving at this centre. We will always do our best to take care of you. If you agree to this treatment, you will also be helping us learn whether the treatment works and how it works to help other patients, though you can withdraw at any time.

**How will your privacy and the confidentiality of your information be protected?** We will use medical information collected or created as part of your medical care, such as medical records and test results that identify you by name or in another way that they request from your physicians and other health care providers. Your medical information will also be shared with appropriate regulatory authorities.

Additionally, all the information or data collected about you to help understand if the therapy is effective will be kept confidential and only be used by the recipients listed here to better understand COVID-19 and its potential treatment(s) and for regulatory oversight of this research.

By signing this form, you give permission to your medical provider to disclose your medical information as described in this form. This permission lasts until the end of the program.

You may take back this permission at any time by telling your doctor. No new medical information will be collected from you after you take back your permission, but any medical information that was already collected will continue to be used and shared as needed for the scientific integrity of the program.

**Your signature documents permission for you (or the patient) to take part in this program.**

Printed Name of Patient: \_\_\_\_\_ Signature: \_\_\_\_\_

Date: \_\_\_\_\_ Time: \_\_\_\_\_ am/pm (Patient or Authorized Representative)

**Person Obtaining Consent**

I have explained the research to the patient/authorized representative and have answered all questions about this research to the best of my ability.

Date: \_\_\_\_\_ Time: \_\_\_\_\_ am/pm

Printed Name: \_\_\_\_\_ Signature: \_\_\_\_\_

**PATIENT CONSENT AND PRIVACY AUTHORIZATION FORM FOR LESS THAN 21 YEARS**

**Title: COVID-19 Convalescent Plasma Treatment in SARS-CoV-2 Infected Patients: Multicenter Interventional Study**

Please read this information carefully. It tells you important things about this research for use of the investigational product, Convalescent Plasma, for patients with COVID-19. A member of the clinical staff will talk to you about taking part in this research. If you have questions at any time, please ask us. Feel free to discuss the research with your family, friends, and healthcare provider before you make your decision. **NOTE:** If you are a family member or legally authorized representative signing this consent form for someone else, “you” in the consent form refers to the patient with COVID-19.

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**Your signature documents permission for you (or the patient) to take part in this program.**

Printed Name of Patient guardian: \_\_\_\_\_ Signature: \_\_\_\_\_

Date: \_\_\_\_\_ Time: \_\_\_\_\_ am/pm (Patient guardian)

**Person Obtaining Consent**

I have explained the research to the patient/authorized representative and have answered all questions about this research to the best of my ability.

Date: \_\_\_\_\_ Time: \_\_\_\_\_ am/pm

Printed Name: \_\_\_\_\_ Signature: \_\_\_\_\_