



## GUIDE ON THE COMPASSIONATE USE OF CONVALESCENT PLASMA THERAPY FOR COVID-19

UP-Philippine General Hospital Technical Working Group on Convalescent Plasma Therapy

*Disclaimer: This guide is intended for use in the Philippine General Hospital for treatment of severe to life-threatening cases of COVID-19 (under compassionate use) with convalescent plasma therapy. Due to the technical requirements to facilitate safe blood collection, processing and handling, these guidelines may not be fully applicable in other centers. COVID-19 is an evolving disease. Information herewith is updated as of April 8, 2020.*

### What's new in V2.0?

An updated version (V2.0) is being released to incorporate new and evolving best practices in the use of convalescent plasma therapy to better suit the needs of our COVID-19 patients. The updated guide includes the US Food and Drug Administration expanded recommendations for donor eligibility and their pathways for administering or studying the use of COVID-19 convalescent plasma as of April 3, 2020. The guide below has also been reviewed by and discussed with World Health Organization representatives and experts as of April 7, 2020.

Convalescent plasma is plasma taken from a person who has recovered from an infection and contains neutralizing antibodies against the said infection. Giving convalescent plasma to susceptible individuals or infected patients is a form of passive antibody therapy traced back as early as the 20<sup>th</sup> century<sup>[i],[ii]</sup>. The use of convalescent plasma (collected from recovered patients) has been studied in outbreaks of other respiratory infections (i.e., H1N1 influenza virus pandemic, 2003 SARS-CoV-1 epidemic, and the 2012 MERS-CoV epidemic with promising results<sup>[iii],[iv],[v]</sup>. It is therefore one investigational treatment being explored for COVID-19 with small studies showing encouraging results<sup>[vi]</sup>. In the case of SARS-CoV-2, convalescent plasma therapy is expected to provide protection by viral neutralization and antibody-dependent cytotoxicity/phagocytosis<sup>[vii]</sup>. Large clinical trials are currently underway to evaluate its role in the management of COVID-19<sup>[viii],[ix],[x]</sup>. There is also currently a local clinical study in this institution being designed to assess the safety and efficacy of convalescent plasma among hospitalized COVID-19 patients in preventing ICU admission.

The use of convalescent plasma therapy therefore remains an **experimental treatment** at this time and is not included in interim clinical guidelines of the World Health Organization. However, the US FDA recently released an emergency investigational new drug (IND) application process to facilitate access to COVID-19 convalescent plasma for use in patients with serious or immediately life-threatening COVID-19 infections outside of clinical trials and is continually updating their recommendations as new evidence and best practices come into light<sup>[xi]</sup>. In line with this and the preliminary evidence for safety and efficacy of convalescent plasma therapy for COVID-19, the compassionate use of convalescent plasma therapy may be justifiable for use among patients with severe and life-threatening disease in the absence of any other effective therapy.

### Eligible patients for use of convalescent plasma therapy

- Adult patient with laboratory confirmed COVID-19
- Severe or immediately life-threatening disease

Severe Disease (one or more of the following)	Life-threatening Disease (one or more of the following)
<input type="checkbox"/> Dyspnea <input type="checkbox"/> Respiratory rate $\geq 30$ /min <input type="checkbox"/> Oxygen saturation $\leq 93\%$ <input type="checkbox"/> PaO <sub>2</sub> /FiO <sub>2</sub> ratio $< 300$ and/or <input type="checkbox"/> Lung infiltrates $> 50\%$ within 24 to 48 hours	<input type="checkbox"/> Respiratory failure <input type="checkbox"/> Septic shock and/or <input type="checkbox"/> Multiple organ dysfunction or failure

- Within 3 to 21 days from onset of symptoms
- Not a diagnosed case of IgA deficiency
- Must be able to provide **informed consent** (see *attached*). In the event that the patient cannot provide consent, next of kin or legal surrogate decision maker should provide consent

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### Eligible donors for COVID-19 convalescent plasma

- Must have passed the standard DOH prescribed donor history questionnaires, where applicable
- Patients with evidence of prior COVID-19 disease and have recovered from the disease (*based on the following order of priority*)

1st priority	<ul style="list-style-type: none"> <li>• Previously diagnosed with COVID-19 by SARS-CoV-2 RT-PCR</li> <li>• Absence of any clinical evidence of COVID-19 for at least 14 days as determined by a licensed physician</li> <li>• With at least 1 negative SARS-CoV-2 RT-PCR result done on recovery</li> </ul>
2nd priority	<ul style="list-style-type: none"> <li>• Previously diagnosed with COVID-19 by SARS-CoV-2 RT-PCR</li> <li>• Absence of any clinical evidence of COVID-19 for at least 28 days as determined by a licensed physician</li> <li>• Even without a negative SARS-CoV-2 RT-PCR result done on recovery</li> </ul>
3rd priority	<ul style="list-style-type: none"> <li>• No SARS-CoV-2 RT-PCR test done to document disease</li> <li>• Absence of any clinical evidence of COVID-19 for at least 28 days as determined by a licensed physician</li> <li>• Positive result for anti-SARS-CoV-2 IgG antibody-based test done on recovery</li> </ul>

- Body weight of more than 50 kg
- Any gender. However, the following should be negative for anti-HLA-antibodies:
  - Males with prior history of blood transfusion
  - Females with prior history of blood transfusion and/or previous pregnancy
- Additional laboratory parameters
  1. Hemoglobin greater than or equal to 12.5 g/dL for females or 13 g/dL for males (or hematocrit greater than or equal to 38%)
  2. Platelet count more than or equal to 150,000
  3. Once anti-SARS-CoV-2 antibody titer assays become available, subsequent donors should have anti-SARS-CoV-2 antibody titers of at least 1:160 (samples from donors prior to availability for antibody titer testing will be saved and will be tested once assays become available)
- Must have signed the informed consent for donation

### Donor screening procedure

1. Risk assessment using DOH prescribed donor history questionnaires except those risks related to COVID-19 (DOH-DM-2020-0142)
2. Informed consent process
3. Donor exclusion based on the DOH NVBSP Manual of Blood Donor Selection
4. Pre-donation testing
  - a. Negative antibody screen
  - b. Non-reactive serologic testing to HBsAg, HCVAb, HIV, syphilis and malaria
  - c. Negative anti-HLA (I and II) antibodies for female donors with prior pregnancy and/or prior blood transfusion and male donors with prior blood transfusion

### Plasma collection

1. Whole blood donation
  - For first time donors



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- Blood will be collected by a trained blood bank staff operating under standard operating procedures and will be processed into leukodepleted convalescent plasma about 200-250 mL, frozen using standard blood bank procedures and stored at  $\leq -20^{\circ}\text{C}$  but not below  $-65^{\circ}\text{C}$  for up to 12 months
  - Packed red cells will be stored for future use
  - Pathogen reduction will be done once available
  - Convalescent plasma will be labelled properly
  - These patients may donate again by pheresis after 8 weeks
2. Apheresis
- For donors with prior whole blood donation or first-time donors who prefer apheresis procedure rather than whole blood donation.
  - About 500 mL of plasma will be collected by apheresis by a trained blood bank staff operating under standard operating procedures
  - Plasma will then be divided into two aliquots (~250 mL each) and will be frozen using standard blood bank procedures and stored at  $\leq -20^{\circ}\text{C}$  but not below  $-65^{\circ}\text{C}$  for up to 12 months
  - Pathogen reduction will be done once available
  - Convalescent plasma will be labeled properly
  - Plasma may be collected as frequently as twice every month (every 2 weeks) and should not exceed a total of 12 liters in a 12-month period
  - At the time of initial plasmapheresis and at 4-month intervals for donors undergoing serial (large-volume) plasmapheresis (donors undergoing plasmapheresis more often than once every 4 weeks), serum or plasma shall be tested for total protein and for serum protein electrophoresis or for quantitative immunoglobulins. Results must be within normal limits.

**Transfusion procedure**

1. Choose a type-specific properly-labeled unit using the table below. Perform reverse typing. No need for minor crossmatching.

<i>Recipient Blood Type</i>	<i>Plasma Blood Type</i>
A	A, AB
B	B, AB
AB	AB
O	O, A, B, AB

2. Thaw frozen plasma at  $37^{\circ}\text{C}$
3. Transfuse 2 aliquots of plasma (250 mL x 2) per patient
  - a. Transfuse first aliquot for 2-3 hours (~1.4 to 2 mL/min)
  - b. Transfuse second aliquot at same rate 2 hours after completion of first aliquot
4. For patients at high-risk for volume overload, may consider increasing the interval between two aliquots and/or giving intravenous dose of diuretics
5. Time at start and end of each infusion should be recorded

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6. Vital signs should be measured immediately prior to infusion, 10-20 minutes after start of infusion, at completion of infusion and 30-60 minutes after the end of infusion
7. Pretreatment to minimize transfusion reactions (e.g., paracetamol, diphenhydramine) may be given per clinical care team discretion
8. If an adverse event develops during infusion, the infusion may be slowed or stopped as per clinical care team's discretion. Transfusion of convalescent plasma should be halted if any of the following manifestations of anaphylaxis develop and will not be restarted:
  - a. Skin or mucous membrane manifestations: hives, pruritus, flushing, swollen lips, tongue or uvula
  - b. Respiratory compromise: dyspnea, wheezing, stridor, hypoxemia
  - c. Decrease in systolic blood pressure to <90 mmHg or >30% decrease from baseline or a diastolic drop of >30% from baseline
  - d. Tachycardia with an increase in resting heart rate to >130 bpm; or bradycardia <40 bpm that is associated with dizziness, nausea or feeling faint
  - e. Any other symptom which the good clinical judgment of the physician warrants halting the infusion (i.e., rapid onset of gastrointestinal symptoms, etc.).
9. Patients receiving convalescent plasma from recovered COVID-19 patients should be closely clinically monitored using standard pathways to assess the effectiveness of the intervention.

### Known potential risks

- Theoretical risk of antibody-mediated enhancement of infection (ADE). This phenomenon may occur with several viral diseases characterized by disease enhancement in the presence of certain antibodies<sup>[xii]</sup>. Available evidence from use of convalescent plasma in SARS1 and MERS patients however suggest that it is safe. Nevertheless, caution and vigilance will be important in assessing for any evidence of enhanced infection.
- Attenuation of immune response which would leave patients vulnerable to subsequent infection<sup>[xiii]</sup>. However, this concern seems modest compared to the possibility of recovery from severe or life-threatening disease. If this theoretical concern is proven real, recipients could be vaccinated against COVID-19 when this becomes available.
- Transfusion-related risks such as allergic transfusion reactions, anaphylaxis, febrile reactions, transfusion-related acute lung injury (TRALI), transfusion-associated cardiac overload (TACO), and ABO-incompatibility hemolysis. These risks will be mitigated by following standard blood donation, processing and transfusion protocols.

### Potential benefit

- Given the historical benefit in other several viral infections and anecdotal data showing efficacy of the use of convalescent plasma for COVID-19 patients with critical illness, the benefits of its use may outweigh the aforementioned risks.
- As always, a risk-benefit assessment must be done on all patients being considered for convalescent plasma therapy.

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[i] Marano G, Vaglio S, Pupella S, et al. Convalescent plasma: new evidence for an old therapeutic tool. *Blood Transfus.* 2016;14(2):152-157.

[ii] Casadevall A, Scharff MD. Return to the past: the case for antibody-based therapies in infectious diseases. *Clin Infect Dis.* 1995;21(1):150-161.



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- [iii] Hung I, To KKW, Lee CK, et al. Convalescent plasma treatment reduced mortality in patients with severe pandemic influenza A (H1N1) 2009 virus infection. *Clin Infect Dis*. 2011;52(4):447-456.
- [iv] Mair-Jenkins J, Saavedra-Campos M, Baillie JK, et al. The effectiveness of convalescent plasma and hyperimmune immunoglobulin for the treatment of severe acute respiratory infections of viral etiology: a systematic review and exploratory meta-analysis. *J Infect Dis*. 2015;211(1):80-90.
- [v] Cheng Y, Wong R, Soo Y, et al. Use of convalescent plasma therapy in SARS patients in Hong Kong. *Eur J Clin Microbiol Infect Dis*. 2005;24(1):44-6.
- [vi] Shen C, Wang Z, Zhao F, et al. Treatment of 5 critically ill patients with COVID-19 with convalescent plasma. 2020. Doi:10.1001/jama.2020.4783.
- [vii] Casadevall A, Pirofski L. The convalescent sera option for containing COVID-19. *J Clin Invest*. 2020. <https://doi.org/10.1172/JCI138003>.
- [viii] <https://clinicaltrials.gov/ct2/show/study/NCT04292340?term=convalescent+plasma&draw=2>
- [ix] <https://clinicaltrials.gov/ct2/show/NCT04321421?term=COV19-PLASMA&draw=2&rank=1>
- [x] <http://www.chictr.org.cn/showprojen.aspx?proj=50696>
- [xi] <https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-center/revised-information-investigational-covid-19-convalescent-plasma>
- [xii] Sullivan NJ. Antibody-mediated enhancement of viral disease. *Curr Top Microbiol Immunol*. 2001;260:145-69.
- [xiii] Crowe JE, Firestone CY, Murphy BR. Passively acquired antibodies suppress humoral but not cell-mediated immunity in mice immunized with live attenuated respiratory syncytial virus vaccines. *J Immunol*. 2001;167(7):3910-3918.

**WORKFLOW FOR COMPASSIONATE USE OF CONVALESCENT PLASMA FOR COVID-19 PATIENTS**

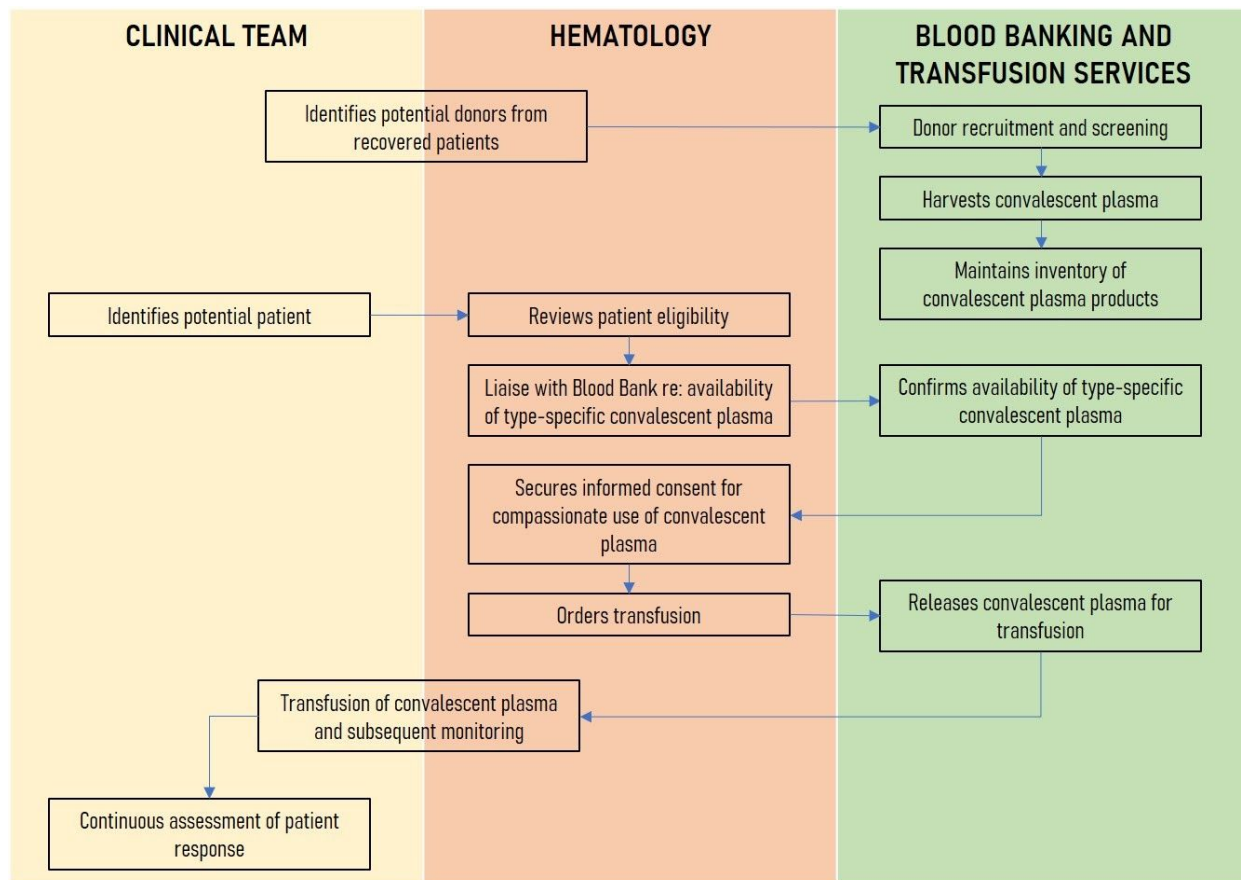


Figure 1. Recommended workflow for compassionate use of convalescent plasma for COVID-19 patients

*For referrals for convalescent plasma therapy in UP-PGH, please contact the following:*

**UP-PGH TWG for Convalescent Plasma Hotline**

+63 923 965 3583

*To refer possible donors, please contact the following:*

**UP-PGH Bayanihan Hotline**

155-200

or

**UP-PGH Blood Banking and Transfusion Services**

+63 917 805 3207

*For other non-urgent related inquiries:*

Please email [pgh.hematology@gmail.com](mailto:pgh.hematology@gmail.com)



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### **Consent Form for Compassionate Use of Convalescent Plasma in Critically Ill COVID-19 Patients**

Dr. \_\_\_\_\_ [Name of physician] is offering to treat you, your family member (in which case the word “you” will refer to “your family member” throughout this document), or the person you represent (in which case the word “you” will refer to the person you are representing) with convalescent plasma because you have a serious condition called Coronavirus Disease 2019 or COVID-19 and there are no standard acceptable options.

#### **What you should know about this experimental treatment?**

- This treatment has not been approved by the Food and Drug Administration of the Philippines.
- This treatment is considered experimental.
- This treatment is not research and you will not be considered a research subject.
- Someone will explain this treatment to you.
- You volunteer to get this treatment.
- Whether or not you get this treatment is up to you.
- You can choose not to get this treatment.
- You can agree to get this treatment now and later change your mind.
- If you do change your mind, contact your doctor right away.
- Whatever you decide, it will not be held against you.
- Feel free to ask all the questions you want before you decide.

#### **How long will this experimental treatment last?**

We expect that the experimental treatment will last for a few hours.

#### **What happens if I get this experimental treatment?**

The process of this experimental treatment will be explained further to you by Dr. \_\_\_\_\_.

Based on literature review, there is a theoretical risk of antibody-mediated enhancement of infection (ADE). This phenomenon may occur with several viral diseases characterized by disease enhancement in the presence of certain antibodies. Available evidence from use of convalescent plasma in SARS1 and MERS patients however suggest that it is safe. Nevertheless, caution and vigilance will be important in assessing for any evidence of enhanced infection.

Another possibility is an attenuation of immune response which would leave patients vulnerable to subsequent infection. However, this concern seems modest compared to the possibility of recovery from severe or life-threatening disease. If this theoretical concern is proven real, recipients could be vaccinated against COVID-19 when this becomes available.

Lastly, there may also be transfusion-related risks such as allergic transfusion reactions, anaphylaxis, febrile reactions, transfusion-related acute lung injury (TRALI), transfusion-associated cardiac overload





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(TACO), and ABO-incompatibility hemolysis. These risks will be mitigated by following standard blood donation, processing, and transfusion protocols.

### **Is there any way this experimental treatment could be bad for me?**

This treatment may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

If you are or become pregnant, this treatment may hurt your baby or your pregnancy in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

Getting this treatment may lead to added costs to you. Insurance may not pay for this treatment because it is considered experimental.

### **Can this experimental treatment help me?**

We cannot promise that this treatment will help you. The goal of this treatment is to give you neutralizing antibodies against the SARS-CoV-2 that can hopefully ameliorate your condition.

### **What else do I need to know?**

If you are injured or made sick from taking part in this treatment, medical care will be provided. You may get in touch with your doctor for more information.

### **Who can I talk to?**

If you have questions, concerns, or complaints, or think the treatment has hurt you, you can talk to your doctor at \_\_\_\_\_. **[Insert contact information]**

### **Additional questions (if any)**





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Your signature on this consent form signifies the following:

1. That all of the details in the process, the benefits and the possible risks in receiving convalescent plasma have been explained to you.
2. That all your questions on the use of convalescent plasma have been answered.
3. That you are giving consent to accept this form of experimental treatment.

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Signature of person providing consent  
*(patient, legally authorized representative, parent, or guardian)*

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Date

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Printed complete name of patient

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Printed name of person providing consent, if patient is  
unable to consent

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Signature of person obtaining consent

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Date

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Printed name of person obtaining consent



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### Pahintulot para sa Paggamot Gamit ang Convalescent Plasma Therapy Para sa Malubhang COVID-19

Iminumungkahi ni Dr. \_\_\_\_\_ **[Pangalan ng manggagamot]** na gamutin ka, ang iyong anak (kung saan ang salitang “iyo” ay tumutukoy sa “iyong anak” na nakasaad sa buong kasulatang ito), o ang taong iyong kinakatawan (kung saan ang salitang “iyo” ay tumutukoy sa taong iyong kinakatawan sa buong kasulatang ito) gamit ang “Convalescent Plasma” sa kadahilanang mayroon kang malubhang karamdamang tinatawag na Coronavirus Disease 2019 o COVID-19, isang kundisyon na walang pamantayan ng pangangalaga sa kasalukuyan.

#### Anu-ano ang iyong dapat malaman ukol sa eksperimental na gamutan?

- Ang gamutang ito ay hindi pa aprubado ng *Food and Drug Administration of the Philippines*.
- Ang gamutang ito ay nagamit na sa mga pasyenteng may COVID-19 sa ibang bansa ngunit itinuturing na eksperimental pa rin sa panahong ito.
- Ito ay karagdagang gamutan lamang. Magpapatuloy pa din ang ibang gamutang ibinibigay sa iyo.
- Ang gamutang ito ay hindi pagsasaliksik at hindi ka itinuturing na kalahok sa pananaliksik.
- May magpapaliwanag sa iyo ng gamutang ito.
- Ikaw ay boluntaryong tumatanggap ng gamutang ito.
- Ang desisyon ng pagtanggap o hindi pagtanggap ng gamutang ito ay nakasalalay sa iyo.
- Maaari mong piliin na hindi tumanggap ng gamutang ito.
- Maaari kang pumayag na tumanggap ng gamutang ito sa ngayon at magbago ng iyong desisyon sa anumang panahon.
- Kung sakaling magbago ang iyong isip, makipag-ugnayan kaagad sa iyong doctor.
- Kung anuman ang iyong desisyon, hindi ito gagamitin laban sa iyo.
- Huwag mag-atubiling magtanong or humingi ng paglilinaw bago magpasya.

#### Gaano katagal ang gamutang ito?

Inaasahan namin na ang gamutang ito ay magaganap sa loob ng ilang oras lamang.

#### Anong mangyayari kung ako ay sumailalim sa gamutang ito?

Ang proseso ng gamutan ay ipapaliwanag sa iyo ni Dr. \_\_\_\_\_ **[Pangalan ng manggagamot]**.



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Batay sa mga nakalap na impormasyon mula sa mga siyentipikong report na gumagamit ng “convalescent plasma” sa mga pasyenteng may malubhang lagay dahil sa COVID-19, ang mga benepisyong makukuha sa paggamit nito ay nangingibabaw sa mga naitalang mga panganib.

Ang isa sa mga naitalang posibleng panganib na maaaring maidulot ng pagbigay ng “convalescent plasma” ay ang magpalubha ng kasalukuyang impeksyon. Subalit, batay sa mga ebidensya ng paggamit ng “convalescent plasma” sa mga pasyenteng may SARS1 at MERS-COV, ito ay ligtas na gamitin. Ang isa pang posibleng panganib sa pagbigay ng “convalescent plasma” ay dulot ng mismong pagsalin ng plasma tulad ng pangangati at pagkakaroon ng pamamantal (allergic transfusion reactions), pangangati, pamamaga ng labi at dila, paghirap sa paghinga, at pagbagsak ng presyon sa dugo (anaphylaxis), paglagnat (febrile reactions), transfusion-related acute lung injury, transfusion-associated cardiac overload, at pagkasira ng pulang dugo dulot ng hindi pagkakatugma ng blood type (ABO-incompatibility hemolysis). Ngunit huwag mag-alala sapagkat ang mga panganib na ito ay madalang mangyari dahil sa mahigpit na pagsunod sa mga pamantayan ng donasyon, pagproseso at pagsalin ng dugo.

### **May pagkakataon ba na ang eksperimental na gamutang ito ay maaaring ikasama ng lagay ko?**

Ang gamutang ito ay maaaring makasama sa iyo sa mga paraang hindi pa natutuklasan o inaasahan. Maaari itong magdulot ng bahagyang abala or kaya naman ay malubhang epekto na maaaring mauwi sa pagkamatay.

Kung ikaw ay buntis o mabuntis habang tumatanggap ng gamutang ito, ito ay maaaring makasama sa iyong sanggol o sa iyong pagbubuntis sa mga paraang hindi pa natutuklasan. Maaari itong magdulot ng bahagyang abala or kaya naman ay malubhang epekto na maaaring mauwi sa pagkamatay.

Ang pagtanggap ng gamutang ito ay maaaring dumagdag sa iyong gastusin. Hindi sakop ng anumang insurance ang ganitong uri ng gamutan sa panahong ito.

### **Matutulungan ba ako ng eksperimental na gamutan?**

Hindi namin maipapangako na tiyak kang matutulungan ng gamutang ito. Ang layunin ng gamutang ito ay mabigyan ang iyong katawan ng “neutralizing antibodies” laban sa SARS-CoV-2 na maaaring makatulong sa iyong paggaling.



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### **Anu-ano pa ang dapat kong malaman?**

Kung ikaw ay magkaroon ng karagdagang karamdaman dulot ng pagtanggap ng gamutang ito, ikaw ang makakatanggap ng naaangkop na atensyong medikal. Makipag-usap sa iyong doktor para sa karagdagang impormasyon.

### **Sino ang maaari kong kausapin?**

Kung ikaw ay may mga katanungan, alalahanin, o hinaing, o kaya naman ay may panibagong nararamdaman na sa iyong palagay ay dahil sa pagtanggap ng gamutang ito, maaari mong kausapin ang iyong doktor sa \_\_\_\_\_. [Insert contact information]

Mga karagdagang katanungan:



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Ang iyong paglagda sa kasulatang ito ay nagpapahiwatig ng mga sumusunod:

1. Naipaliwanag sa iyo ang proseso, mga benepisyo at mga maaaring panganib ng “convalescent plasma”
2. Nasagot ang iyong mga katanungan tungkol sa paggamit ng “convalescent plasma”
3. **PAGBIBIGAY NG IYONG PAHINTULOT** sa paggamit ng eksperimental na gamutang ito

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Lagda ng taong nagbibigay ng pahintulot  
(*pasyente, kinatawan ng legal na kinatawan, magulang, o tagapag-alaga*)

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Petsa

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Buong pangalan ng pasyente

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Buong pangalan ng taong nagbigay ng pahintulot, kung hindi kaya ng pasyente

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Pangalan at Lagda ng taong nagpaliwang at kumuha ng pahintulot

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Petsa

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Pangalan at Lagda ng Pangunahing Manggagamot



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**ELIGIBILITY QUESTIONNAIRE FOR COVID-19 CONVALESCENT PLASMA DONATION**

Surname:		Full name:		Middle name:	
Age/Sex:		Birthdate:		Civil Status:	
Weight:		Nationality:		Tel./Cel. #:	
Complete Address:					

Instructions: Place a check (✓) on the appropriate box:

Yes	No	QUESTION
		1. Have you been diagnosed by COVID-19, confirmed by RT-PCR? If <b>YES</b> , answer the following:
		<ul style="list-style-type: none"> <li>• Institution and date when the swab taken yielded <b>POSITIVE</b> COVID-19 result:</li> </ul>
		<ul style="list-style-type: none"> <li>• Institution and Date(s) when the swab(s) yielded <b>NEGATIVE</b> COVID-19 result:</li> </ul>
		<ul style="list-style-type: none"> <li>• Date when you became asymptomatic</li> </ul>
		<ul style="list-style-type: none"> <li>• Date of Hospital discharge (<i>if applicable</i>)</li> </ul>
		3. Have you had a history of blood transfusion? If <b>YES</b> , answer the following:
		Date of last blood transfusion and indication
		4. For the past <b>2 weeks</b> have you ever had the following?
		a. Cough
		b. Fever ( $\geq 38.0^\circ$ )
		c. Difficulty breathing
		d. Diarrhea



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		e. Fatigue	
		f. Body aches and pain	
		5. IF female, have you ever been pregnant?	

Place a check (✓) on the appropriate box:

Risk stratification of previous COVID-19 infection (to be accomplished by Blood Donor Center Staff)	
	Mild: COVID-19 RT-PCR positive, home quarantine
	Moderate: COVID-19 RT-PCR positive, hospital admission
	Severe: COVID-19 RT-PCR positive, ICU admission

Laboratory results (to be accomplished by Blood Donor Center Staff)	
CBC	
Hemoglobin	
Hematocrit	
Platelet	
anti-SARS-CoV-2 antibody titers	
Serology	
Hep	

**Informed Consent Form**





## **GUIDE ON THE COMPASSIONATE USE OF CONVALESCENT PLASMA THERAPY FOR COVID-19**

*UP-Philippine General Hospital Technical Working Group on Convalescent Plasma Therapy*

### **Convalescent Plasma Donor**

*Format adapted from Interim Guidance for National Health Authorities and Blood Transfusion Services: Use of Convalescent Whole Blood or Plasma Collected from Patients Recovered from Ebola Virus Disease for Transfusion, as an Empirical Treatment during Outbreaks (WHO, 2014)*

#### **1. General information about Coronavirus disease 2019 (COVID-19) and convalescent whole blood or plasma for COVID-19 treatment**

Coronavirus disease 2019 (COVID-19) is an emerging viral disease not previously documented in humans until December 2019. It is transmitted when an infected individual talks, sneezes or coughs producing 'droplets' containing the virus. These droplets can then be inhaled by another person. Some of the most common symptoms of the disease include fever, cough and fatigue. Severe cases rapidly progress to acute respiratory distress syndrome.

To date, no drug or vaccine has been approved to treat COVID-19. Only a few primary prevention measures have been established focusing on avoiding direct contact with people infected with the virus and practice of proper hand hygiene. If a treatment for COVID-19 could be found, it would save many lives.

People like you, who have recovered from COVID-19, did so, because your body was able to fight the disease and now your blood contains substances which are capable of fighting COVID-19. Prior studies have presented evidence that patients who currently have the disease, could improve faster if they received some of your blood or plasma (the liquid part of your blood) that has the ability to fight COVID-19. But we don't know this for sure. It is possible that a patient with COVID-19 may not recover, even after receiving blood from a person who has recovered from COVID-19. Because we don't have any other treatment option at present, we would like to try it in case it is successful, as it has been for certain other viruses. You could think of this as a gift to another person. To try out this treatment, we will first ask you to allow us to review your medical records from the health facility which treated you for COVID-19, to assess if you can safely donate blood or plasma.

#### **2. What will happen if you agree to donate blood?**

##### **A) Screening and testing.**

Donating blood is very simple. We will ask you to go to the blood donation facility.

1. You will be given a questionnaire on your eligibility to donate COVID-19 convalescent plasma.
2. Another questionnaire will be given to you. These questions are designed to ensure your safety as a donor as well as the safety of the patients who will receive the plasma.
3. Blood samples will be taken from you to determine your blood type and test your blood for the presence of TTI and COVID-19 status (or if you have fully recovered from COVID-19?). Other tests will also be done to ensure your safety and the plasma recipient.
4. If you are cleared you will proceed to the collection.

##### **B) Blood Collection**



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Depending on your classification you can donate by plasmapheresis or whole blood collection. The donor coordinator will explain the process to you.

### *Plasmapheresis*

This is a method of plasma collection where blood is drawn from the donor and processed in a machine. A small tube will be connected to a machine that will collect the liquid part of the blood into a separate bag, and return the red part of your blood back to your body. To stop the blood from clotting, a liquid, known as an anticoagulant, will be automatically mixed with the blood as it is pumped from the body into the machine. The total plasma volume collected is about 500 mL. The entire procedure takes approximately 1 hour and 15 minutes. This is a closed and sterile system.

### *Whole blood donation*

This is the usual blood donation where a needle is inserted into your vein (or blood vessel) and about 450 ml (should we say 467 ml) of blood is drawn from the donor. The blood collected will then be processed into blood components; plasma and packed red blood cells. It is the plasma component that will be given to a COVID-19 patient. The entire blood collection process will take no more than 15 minutes.

The following are the steps in blood collection:

1. Wash arms with soap and water. Wipe it dry with the tissue provided.
2. Drink water or juice given to you.
3. The nurse/doctor will then ask you to lie on a couch or clinic bed.
4. The inner area of one of your elbows will be cleaned with an antiseptic solution before a trained health worker inserts a sterile needle. If you are donating by plasmapheresis the needle is connected to a tube that goes to the apheresis machine. For whole blood collection the needle is connected to a small tube and the blood goes inside the blood bag.
5. After the blood or plasma collection, the needle will be withdrawn. Apply pressure to the site.
6. A dressing will be applied.
7. You will be given light refreshments after the procedure.
8. Do not stand up or leave the donation area until you are told to do so.

### **C) Post donation**

After resting for about 15-30 minutes, you will be able to return to your normal activities, although you should avoid strenuous activities for the rest of the day. You should drink plenty of fluids over the next 24 hours. Your body will replace the lost fluid within about 36 hours. Avoid smoking at least 4 hours after the donation. Drinking alcoholic beverages is discouraged in the next 24 hours. If you feel anything unusual after you have left the donation center, please call the donor coordinator.

### **D) Storage of blood or plasma units**

The blood that has been collected will be stored in a refrigerator with an identification number and will be processed into frozen plasma. If plasma has been collected or separated from your whole blood donation, it will also be stored in a refrigerator or freezer. It will not have your name on it. When there is a patient who is likely to benefit from the use of plasma donated by you, it will be taken out from the stock, and



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brought to room temperature, and then given to the patient through a vein. We will keep a close watch on the patient and record everything, so that we learn from the experience and know more about its use in the treatment of COVID-19.

### **3. Possible risks and discomforts**

Taking blood from your arm may sometimes cause bruising, mild pain or discomfort and in very rare circumstances, infection. Others experience symptoms such as nausea and light-headedness. These last for only a few minutes and quickly subside. We will take all preventive measures to minimize these risks.

### **4. Confidentiality**

Any information that you provide and all test results will be treated confidentially. The medical staff who test your blood have the responsibility to inform you of all the blood test results, and to advise you on any treatment they think you will require.

### **5. Will I know who receives my blood?**

A patient with early COVID-19 with a compatible blood type to yours would receive your blood. Your name will not be on the blood or plasma you have donated, it will just be identified with a unique donation number. You will be assured that it will be used for a patient who requires it and all information about you and your donation will remain confidential.

### **6. Will the person who receives the blood know who has provided it?**

No. In accordance with Data Privacy Act of 2012 (RA 10173), no one, including the person who receives your blood, will know who has provided the blood. Be assured that the blood or plasma that we collect will be treated with respect.

### **7. Expenses and payments**

There will be no charges to you for any cost related to this donation. There will be no payment for you to participate in this donation either.

### **8. Participation and withdrawal from donation**

You are free to decide whether or not to donate blood or plasma. If you do not meet the donor suitability criteria, you will be immediately notified by the Blood Donor Center staff on duty.

Once your blood and/or plasma has been collected, you can request that it is withdrawn at any time prior to it being transfused to a patient by informing the blood bank or the donor coordinator. You cannot request that your blood or plasma donation should not be used for transfusion, once it has been given to a patient. Your decision to request the discard of your blood or plasma, if it has not been transfused, will not affect your future care.



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**9. Who to contact**

If you have any questions, feel free to contact us at the PGH Blood Donor Center:

**SANDY C. MAGANITO, MD**  
Department of Laboratories  
+639178053207

“I, \_\_\_\_\_, certify that I am the person referred to in all the entries, which were read and well understood by me. It is my free and voluntary act to donate my blood, aware of its risks during and after extraction. The same have been explained to me in the understandable language and dialect that I speak.”

I am voluntarily giving my blood through the Philippine General Hospital Blood Bank. I understand that my blood will be tested for Blood Type, Hemoglobin, Malaria, Syphilis, Hepatitis B, Hepatitis C and HIV and no official result will be released to me. If the result is reactive, I agree to be referred to the appropriate facility for counseling and further management.

**I certify that I have to the best of my knowledge, truthfully answered the above questions.”**

\_\_\_\_\_  
Signature of person providing consent  
(patient, legally authorized representative, parent, or guardian)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed name of patient

\_\_\_\_\_  
Printed name of person providing consent, if patient is unable to consent

\_\_\_\_\_

\_\_\_\_\_



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Signature of person obtaining consent

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Date

---

Printed name of person obtaining consent

**CONFIDENTIAL UNIT EXCLUSION (CUE):**

If at any point during or after your blood donation, you realize that your blood may not be safe for transfusion, please inform the Blood Service Facility staff immediately and sign below.

I will not allow my blood to be given for transfusion \_\_\_\_\_

I will not give blood \_\_\_\_\_



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### **Kasulatan ng Pahintulot Donor ng Convalescent Plasma**

*Halaw sa Interim Guidance for National Health Authorities and Blood Transfusion Services: Use of Convalescent Whole Blood or Plasma Collected from Patients Recovered from Ebola Virus Disease for Transfusion, as an Empirical Treatment during Outbreaks (WHO, 2014). Pagsasalin ni Prof. Odessa Joson (Sentro ng Wikang Filipino -UP Manila)*

#### **1. Pangkalahatang Impormasyon tungkol sa Coronavirus disease 2019 (COVID-19) at convalescent whole blood or plasma para sa COVID-19 treatment**

Ang Coronavirus disease 2019 (COVID-19) ay isang bagong viral disease na naidokumento lamang sa tao noong December 2019. Naipapasa ito kapag ang isang taong may COVID-19 ay nagsalita, bumahing, o umubo ng 'droplets' na may dalang virus. Ang droplets na ito ay malalanghap ng ibang tao. Ang ilan sa mga karaniwang sintomas ng COVID-19 ay lagnat, ubo, at panghihina. Ang malulubhang kaso ay nagiging acute respiratory distress syndrome.

Sa kasalukuyan, wala pang gamot o bakuna laban sa COVID-19. May ilang napatunayan nang hakbang para maiwasan ito tulad ng pag-iwas sa malapitang pakikisalamuha sa taong may COVID-19 at regular at wastong paghuhugas ng kamay. Kung makadiskubre ng gamot sa COVID-19, maraming buhay ang maliligtas.

Ang mga taong tulad mo, ay gumaling sa COVID-19 dahil nilabanan ng katawan mo ang impeksiyon. At ngayon ang dugo mo ay may mga bahagi na may kakayahang labanan ang COVID-19. Ang mga naunang pag-aaral ay nagpakita ng ebidensya na ang mga pasyenteng may COVID-19, ay mas mabilis na gagaling kung makakatanggap ng iyong dugo o plasma (ang likidong bahagi ng iyong dugo) na may kakayahang labanan ang COVID-19. Pero hindi pa naman ito natitiyak sa ngayon. Maaring ang isang pasyenteng may COVID-19 ay hindi na gumaling, kahit bigyan ng dugo galing sa isang taong gumaling sa COVID-19. Dahil wala pang ibang gamot sa kasalukuyan, gusto namin subukan ang treatment na ito dahil naging matagumpay ito para sa ilang virus. Maari mong isipin na tulong mo ito sa ibang tao. Para subukan ang treatment na ito, kailangan muna naming suriin kung ligtas kang makakapag-donate ng dugo o plasma. Para magawa ito, hinihingi namin ang iyong pahintulot na makita ang iyong medical records mula sa ospital na tumanggap sa iyo bilang pasyenteng may COVID-19.

#### **2. Ano ang mangyayari kung magdo-donate ka ng dugo?**

##### **A) Iskrining at testing.**

Simple lamang ang pagdo-donate ng dugo. Kailangan mong pumunta sa blood donation facility.

1. Bibigyan ka ng kuwestiyonaryo para malaman kung puwede kang mag-donate ng COVID-19 convalescent plasma.
2. Mayroon pang isang kuwestiyonaryo para matiyak kung ligtas kang makakapag-donate, maging ang kaligtasan ng mga pasyenteng tatanggap ng iyong plasma.
3. Kukunan ka ng dugo para malaman ang iyong blood type at suriin ang iyong dugo para sa



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TTI at COVID-19 status (o para suriin kung tuluyan kang gumaling sa COVID-19?). May iba pang test na gagawin para matiyak ang kaligtasan mo at ng tatanggap ng iyong plasma.

4. Kung bibigyan ka ng clearance, susunod na ang pagkolekta ng dugo.

### **B) Koleksiyon ng Dugo**

Depende sa iyong klasipikasyon, maari kang mag-donate sa pamamagitan ng plasmapheresis o whole blood collection. Ipapaliwanag sa iyo ng donor coordinator ang prosesong ito.

#### *Plasmapheresis*

Isang metodo sa koleksiyon ng plasma kung saan ang nakuhang dugo ay pinoproseso ng isang makina. Isang maliit na tubo ang nakakonekta sa makina na kokolekta sa likidong bahagi ng dugo. Ililipat nito ang likido sa isang bag at ibabalik ang pulang bahagi ng iyong dugo sa iyong katawan. Para hindi mamuo ang dugo, awtomatikong hinahaluhan ito ng isang likido (anticoagulant) habang kinokolekta mula sa iyong katawan patungo sa makina. Ang kabuuang kokolektahing plasma ay 500 mL. Tatagal ang buong proseso sa loob ng 1 oras at 15 minutos. Isa itong sistemang ligtas at malinis.

#### *Whole blood donation*

Ito ang karaniwang proseso ng donasyon ng dugo. Isang karayom ang itutusok sa iyong ugat (o blood vessel) at kukuha ng 450 ml. (o 467ml) na dugo mula sa donor. Paghihiwalayin ang blood components (plasma at packed red blood cells) mula sa iyong dugo. Plasma component ang ibibigay sa pasyenteng may COVID-19. Tatagal ang buong proseso sa loob ng 15 minutos.

Narito ang mga hakbang sa koleksiyon ng dugo:

1. Hugasan ang braso gamit ang sabon at tubig. Punasan ito ng ibibigay na tissue.
2. Inumin ang tubig o juice na ibibigay sa iyo.
3. Pahihigain ka ng nars/doktor sa sofa o clinic bed.
4. Lilinisin ng isang nars/doktor ang looban ang iyong braso gamit ang antiseptic solution bago tusukin ng esteril na karayom. Kung magdo-donate ka sa prosesong plasmapheresis, ang karayom ay nakakabit sa tubo na nakakonekta sa apheresis machine. Kung whole blood collection, ang karayom ay konektado sa isang maliit na tubo at ang dugo ay isasalin sa blood bag.
5. Pagkatapos ng koleksiyon ng dugo o plasma, tatanggalin ang karayom. Kailangan mong diinan ang area na tinurukan ng karayom.
6. Lalagyan ng gasa/bulak ang area na tinurukan ng karayom.
7. Bibigyan ka ng inumin pagkatapos ng procedure. Huwag ka munang tumayo o umalis sa donation area hanggang hindi mo pa kayang tumayo.

### **C.) Pagkatapos mag-donate**

Pagkatapos magpahinga ng 15-30 minutos, maari ka nang bumalik sa normal mong gawain. Gayunpaman, mas maiging umiwas ka muna sa mabibigat na gawain buong araw. Kailangan mong uminom ng maraming tubig sa loob ng 24 oras. Mapapalitan ng iyong katawan ang nawalang likido sa loob ng 36 oras. Huwag manigarilyo sa loob ng 4 na oras pagkatapos mag-donate ng dugo. Huwag din





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uminom ng alak sa loob ng susunod na 24 oras. Kung may nararamdaman kang kakaiba pag-alis mo sa donation center, mangyaring tawagan mo ang donor coordinator.

### **D) Pag-iingat ng dugo o plasma units**

Ang nakolektang dugo ay ilalagay sa isang refrigerator, lalagyan ng identification number, at gagawing frozen plasma. Kung ang plasma ay kinolekta o ihiniwalay mula sa iyong whole blood donation, ilalagay din ito sa refrigerator o freezer. Hindi ito lalagyan ng iyong pangalan. Kapag mayroong pasyente na maaring magbenepisyo mula sa donasyon mong plasma, kukunin ang plasma mula sa refrigerator, ilalagay ito sa room temperature, at ituturok sa ugat ng pasyente. Mahigpit naming babantayan ang pasyente at irekord ang lahat ng mangyayari sa kaniya. Gagawin namin ito para matuto kami sa kaniyang kalagayan at malaman ang gamit nito sa paggamot ng mga pasyenteng may COVID-19.

### **3. Mga Posibleng Panganib**

Ang pagkuha ng dugo mula sa iyong braso ay maaring magdulot ng pasa, kirot, o hapdi at sa bihirang pagkakataon impeksiyon. May ilang tao na nakakaranas ng pagsusuka at pagkahilo. Tatagal lamang ito ng ilang minuto at mabilis ding mawala. Gagawin namin ang lahat para maibsan ang mga panganib na ito.

### **4. Kumpidensiyalidad**

Ituturing na kumpidensiyal ang anumang ibibigay mong impormasyon at test results. Sasabihan ka ng medical staff sa resulta ng blood test, at aabisuhan ka sa mga treatment na maari mo pang kailanganin.

### **5. Malalaman ko ba kung sino ang tatanggap ng aking dugo?**

Isang pasyenteng may COVID-19 na kapareho mo ng blood type ang tatanggap ng iyong dugo. Hindi ilalagay ang pangalan mo sa na-donate na dugo o plasma. Lalagyan lang ito ng donation number. Makakatiyak kang gagamitin ito sa pasyenteng mangngailangan nito, at ang lahat ng impormasyon tungkol sa iyo at iyong donasyon ay mananatiling kumpidensiyal.

### **6. Malalaman ba ng taong tatanggap ng dugo kung sino ang nag-donate nito?**

Hindi. Ayon sa Data Privacy Act of 2012 (RA 10173), walang sino man, kahit ang taong tatanggap ng iyong dugo, ang makakaalam kung sino ang nag-donate ng dugo. Makakatiyak ka na ang dugo o plasma na nakolekta namin ay pahahalagahan at iingatan namin.

### **7. Gastusin at kabayaran**

Hindi ka gagastos para sa iyong donasyon ng dugo. Hindi ka rin babayaran para sa iyong partisipasyon sa donasyong ito.



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### 8. Partisipasyon at Pagbawi ng donasyon

Malaya kang magdesisyon kung gusto mong mag-donate ng dugo o plasma. Kung hindi ka puwedeng maging donor, sasabihan ka agad ng doctor-in-charge.

Kapag nakolekta na ang iyong dugo at/o plasma, maari mo itong bawiin anumang oras bago ito maisalin sa isang pasyente. Kailangan mong sabihin ito sa iyong doktor. Hindi mo na mababawi ang donasyon mong dugo o plasma kapag naisalin na ito sa isang pasyente. Ang desisyon mong bawiin ang iyong dugo o plasma, kung hindi pa naisasalin sa isang pasyente ay hindi makakaapekto sa alagang medikal na kakailanganin mo sa hinaharap.

### 9. Sino ang puwedeng kontakin

Kung mayroon kang mga katanungan, maari mo kaming kontakin sa PGH Blood Donor Center:

**SANDY C. MAGANITO, MD**

Department of Laboratories  
Philippine General Hospital  
+639178053207

“Ako si, \_\_\_\_\_, pinapatunayan kong ako ang taong tinutukoy sa kasulatang ito. Binasa at lubusan kong naiintindihan ang kasulatang ito. Malaya at boluntaryo kong dino-donate ang aking dugo, alam ko ang mga panganib habang kinokolekta at pagkatapos kolektahin ang aking dugo. Ang mga ito ay ipinaliwanag sa akin sa isang wika at dayalekto na naiintindihan at sinasalita ko.”

Boluntaryo kong binibigay ang aking dugo sa Philippine General Hospital Blood Bank. Naiintindihan kong susuriin ang aking dugo para sa Blood Type, Hemoglobin, Malaria, Syphilis, Hepatitis B, Hepatitis C at HIV at hindi ipaalam sa akin ang opisyal na resulta. Kung ang resulta ay reactive, pumapayag akong ma-refer sa angkop na pasilidad para sa counseling at iba pang management.

**Pinapatunayan kong matapat kong sinagot ang mga katanungan sa itaas, sa abot ng aking kaalaman.”**

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Pirma ng Taong Magbibigay ng Pahintulot

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Petsa

(pasyente, legal at awtorisadong representatibo, magulang, o guardian)

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Pangalan ng Pasyente



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Pangalan ng Taong Magbibigay ng Pahintulot, kung hindi  
makakapagbigay ng pahintulot ang pasyente

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Pirma ng Taong Kumuha ng Pahintulot

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Petsa

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Pangalan ng Taong Kumuha ng Pahintulot

**CONFIDENTIAL UNIT EXCLUSION (CUE):**

Kung habang o pagkatapos ng iyong donasyon ng dugo, nalaman mong hindi ito ligtas para isalin,  
ipagbigay-alam agad sa staff ng Blood Service Facility at pumirma sa ibaba.

Hindi ko pinapayagan na isalin ang aking dugo \_\_\_\_\_

Hindi ako magbibigay ng dugo \_\_\_\_\_