NATIONAL BLOOD SERVICE GHANA

Guidelines for the Collection, Processing, Storage and Use of Convalescent Plasma as a Blood Product in Ghana
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<tr>
<td>ADE</td>
<td>Antibody Dependent Enhancement</td>
</tr>
<tr>
<td>COVID-19</td>
<td>Coronavirus Disease 2019</td>
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<tr>
<td>CP</td>
<td>Convalescent Plasma</td>
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<tr>
<td>CWB</td>
<td>Convalescent Whole Blood</td>
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<td>EVD</td>
<td>Ebola virus disease</td>
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<tr>
<td>FDA</td>
<td>Food and Drugs Authority</td>
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<tr>
<td>H1N1</td>
<td>Influenza A Virus Subtype H1N1</td>
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<tr>
<td>HBV</td>
<td>Hepatitis B Virus</td>
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<td>HCV</td>
<td>Hepatitis B Virus</td>
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<tr>
<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
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<td>IgG</td>
<td>Immunoglobulin G</td>
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<tr>
<td>MERS-CoV</td>
<td>Middle East Respiratory Syndrome Coronavirus</td>
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<td>NBS</td>
<td>National Blood Service</td>
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<tr>
<td>RT-PCR</td>
<td>Reverse transcription-polymerase chain reaction</td>
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<tr>
<td>SARS-CoV-1</td>
<td>Severe Acute Respiratory Syndrome Coronavirus 2</td>
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<tr>
<td>SARS-CoV-2</td>
<td>Severe Acute Respiratory Syndrome Coronavirus 2</td>
</tr>
<tr>
<td>TRALI</td>
<td>Transfusion Related Acute Lung Injury</td>
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<td>TTI</td>
<td>Transfusion Transmissible Infection</td>
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<td>WHO</td>
<td>World Health Organization</td>
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1 Introduction

These guidelines have been developed by the National Blood Service of Ghana based on recommendations by the WHO\(^1\), and on current evidence on COVID-19 management. The guidelines outline the steps required to collect COVID-19 convalescent whole blood (CWB) for processing into COVID-19 convalescent plasma (CP), or COVID-19 convalescent plasma (CP) by plasmapheresis from patients who have recovered from COVID-19 for transfusion to patients with COVID-19, as an empirical treatment. These guidelines cover:

- the identification of patients who have recovered from COVID-19 as potential donors for convalescent whole blood and plasma;
- informed consent and selection of donors;
- determination of donor ABO and Rh ‘D’ group and screening for transfusion transmissible infections (TTI);
- convalescent whole blood and plasma collection and donor care;
- labelling, storage and data collection in blood centres;
- selection of COVID-19 patients for CP transfusion for CP transfusion;
- informed consent of COVID-19 patients;
- patient blood grouping and compatibility testing;
- storage and transportation of CP to the sites where transfusions are to be given;
- the clinical transfusion process;
- data collection at the transfusion site; and
- assessment of the effectiveness of this empirical treatment.

The COVID-19 CWB for processing as CP or apheresis CP should be collected, processed, and stored by Blood Centres capable of implementing the guidance provided in this document, recommended by the National Blood Service and accredited by the Food & Drug Authority (FDA). The COVID-19 CP should be transfused in facilities capable of implementing the guidelines, and approved by the COVID-19 National Case Management Leader. The workflow for collection, processing and transfusion of CP and responsibilities for the various components of these guidelines are illustrated in Figure 1 “Convalescent plasma collections workflow” on page 18 (Appendix 1).

1.1 Background

Ghana recorded the first confirmed cases of the Coronavirus Disease 2019 (COVID-19) caused by the novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) on 12\(^{th}\) March 2020. As on the 20th of April 2020, the number of cases had increased to 1042 confirmed cases with 99 recoveries and 9 deaths. There are currently no proven treatment or prophylaxis options for COVID-19. Convalescent plasma is plasma taken...
from a person who has recovered from an infection and contains antibodies against the said infection. Passive antibody administration through transfusion of convalescent plasma may offer the only short-term strategy to confer immediate immunity to susceptible individuals.\textsuperscript{2} The use of convalescent plasma has been studied in outbreaks of other respiratory infections (i.e., 2009 H1N1 influenza virus pandemic, 2003 SARS-CoV-1 epidemic, and the 2012 MERS-CoV epidemic) with promising results.\textsuperscript{3–5} It is therefore one of the investigational treatments being explored for COVID-19 with small studies showing encouraging results.\textsuperscript{6} Large clinical trials are currently underway to evaluate its role in the management of COVID-19.\textsuperscript{7–9} In 2014, the use of convalescent plasma collected from patients who had recovered from Ebola virus disease was recommended by WHO as an empirical treatment during outbreaks.\textsuperscript{7}

2 Donor selection, screening, donation and handling of blood and plasma units

2.1 Identification of suitable blood or plasma donors among patients recovered from COVID-19

Eligible donors for COVID-19 convalescent plasma:

- Must meet the standard NBS donor eligibility criteria and complete prescribed donor health questionnaire
- Patients with evidence of prior COVID-19 disease and have recovered from the disease:
  - Laboratory evidence of COVID-19, documented by either of the following:
    - Positive RT-PCR test for SARS-CoV-2 at the time of illness
    - Positive serological test for SARS-CoV-2 antibodies after recovery if no diagnostic testing was performed when COVID-19 was suspected
  - Absence of any clinical evidence of COVID-19 for at least 14 days as determined by a licensed physician
  - Proven to have cleared SARS-CoV-2 from nasopharyngeal mucosa by 2 negative RT-PCR results, first PCR test should be at least 14 days after being asymptomatic. The two RT-PCR tests should be at least 7 days apart.

A register or database of patients who have recovered from COVID-19 as potential CWB/CP donors should be created by the COVID-19 case management team, under the responsibility of the National Case Management Leader. Discharge records of COVID-19 recovered patients should be reviewed by clinical management team and the blood centre physician before considering them as potential CWB/CP donors.
Individuals should be virus-free at the time of blood collection to exclude the potential risk posed to blood collections staff and other donors.

2.2 Donor information, consent and selection
When a COVID-19 recovered patient has been identified as a potential donor, the need for collecting his/her whole blood or plasma donation should be explained, emphasizing that this could be useful as an empirical treatment for COVID-19 patients. Potential donors should be informed that there will be no payment made to them for their blood or plasma donation. Only male donors and females without a history of pregnancy will be considered for donating convalescent plasma, to minimise the risk of acute lung injury in recipients. Consenting potential donors will be assessed for suitability to donate blood or plasma through a donor selection process, including general health criteria such as weight ≥50kg, having passed a blood donor questionnaire on medical and social (i.e. behavioural risk factors) history, basic physical examination and haemoglobin estimation. In addition, donors for plasmapheresis should have their heights measured and recorded. The decision to donate blood should be voluntary and informed.

A written informed consent (Appendix 2) should be obtained from the potential donor for donation of a unit of whole blood or plasma by apheresis for transfusion. Donor confidentiality should be maintained to avoid any coercion to donate from the community.

2.3 Testing of donor blood
2.3.1 Pre-donation testing should include:

- Blood screening tests for HIV 1&2, HBV, HCV and Syphilis.
- Haemoglobin estimation performed as part of the initial donor selection process. A lower threshold of 12.0 g/dl for women and 13.0 g/dl for men is recommended for whole blood donation, and 11.5 g/dl for women and 12.5 g/dl for men for apheresis plasma donation.
- COVID-19 Antibody and Testing:
  - SARS-CoV-2 neutralizing antibody titres should be measured and documented. A titre of 1:160 is recommended, but 1:80 may be accepted for transfusion. Where antibody titres cannot immediately be measured, a retention sample from the convalescent plasma donation should be stored for subsequent determination of antibody titres.
SARS-CoV-2 neutralizing antibody titres should be measured and documented. A titre of 1:160 is recommended, but 1:80 may be accepted for transfusion. Where antibody titres cannot immediately be measured, a retention sample from the convalescent plasma donation should be stored for subsequent determination of antibody titres.

SARS-CoV-2 total antibody titres should be measured.

Depending on the test to be performed and the assay system used, either serum or plasma could be used for these tests. Two blood samples of 5ml each should be collected for these tests, one in EDTA for a plasma sample and the other one in a plain tube for a serum sample. Residual serum from these blood samples should be stored in aliquots for retrospective antibody testing or any other tests, as required.

2.3.2 Post-donation Testing
Post-donation testing should be performed on the donated blood and should include:

- Markers for HIV, HBV, HCV and Syphilis.
- ABO blood group
- RhD blood group (for whole blood collections)
- Antibody screening for irregular antibodies.
- Blood group O donations tested for high titre anti-A and anti-B antibodies. High titre anti-A and/or anti-B antibodies in group O plasma units should only be transfused to blood group O recipients.

2.3.3 Archiving of donor sample
Aliquots of donor sample should be appropriately labelled and stored in a designated freezer for a period of 5 to 10 years depending on storage space for future reference. This is to support the investigation into infections or adverse reactions in patients where the transfusion of blood components may be implicated.

All documentation should be properly done to ensure traceability and records well kept.

2.4 Blood collection and donor care
The results of the pre-donation testing should be reviewed to determine if they meet the acceptance criteria. Potential donors who test negative for all TTI tests and meet all other criteria of donor suitability should be selected for donations.

2.4.1 Whole Blood Donation
Whole blood of 450ml should be collected into a double blood bag for the separation into plasma and red cells by centrifugation. Volume of blood collection may vary depending on the age and weight of the donor, but should not exceed 13% of the total
blood volume of the donor. There should be a minimum period of 4-month interval between donations for both males and females.

2.4.2 Plasmapheresis
Where possible CP should be collected by apheresis procedure from suitable donors. Plasmapheresis (rather than whole blood donation) is recommended to optimize the yield of convalescent plasma. Plasmapheresis will enable collection and storage of large volumes of CP that may be used for more than one patient. The total volume of CP collected by apheresis should not exceed 10% the donor’s total blood volume. At any stage in the procedure, the total extracorporeal volume, excluding anticoagulant, should not exceed 15% the donor’s total blood volume. The inter-donation interval for collection of plasma by apheresis should be 2 weeks. The minimum interval before a plasmapheresis donation should be 4 weeks after a whole blood donation or a failed return of red cells during apheresis.

2.4.3 Care of the Donor
The donor should be provided with good care before, during and after the whole blood or plasma donation procedure ensuring confidentiality. Any adverse donor reactions should be adequately and promptly managed and recorded. All existing standard protocols should be adhered to. The protocol on post-donation care of the convalescent plasma donor (Appendix 5) should be adhered to.

Post-donation notification and counselling
Donors with reactive TTI test results should be notified and counselled. They should subsequently be referred to appropriate health-care institutions for further investigation, confirmation, counselling, treatment and care. This should follow existing standard operating procedures. (See Appendix 5)

2.5 Storage of plasma units, inventory management and transportation
2.5.1 Storage of plasma units
CP separated from whole blood donations or collected by apheresis should be frozen and stored for up to 12 months at or below -20°C in a designated temperature-controlled plasma freezer.

2.5.2 Labelling of CP
The unit should be labelled with Component name “Convalescent Plasma” and component code if available according to existing standard operating procedures. Special Donation Number should be created for the blood donation.
Convalescent Whole Blood Processing

CWB should be separated into plasma and CRC by centrifugation according to the existing standard operating procedures. The component CRC should be labelled as CCRC (Convalescent Concentrated Red Cells) and the Plasma as Convalescent Plasma.

Units found to be TTI non-reactive should be labelled with their blood groups, component name, code if available, antibody assay results if available and stored appropriately prior to release.

2.5.3 Inventory management and transportation

Careful inventory management procedures should be in place for CP donations collected or processed, with full consideration of ABO and Rh D blood groups and expiry dates of the CP units.

To minimize wastage due to expiry:

- CP units should be arranged according to blood groups and expiry dates.
- The principle of First-in, First-out (FIFO) should be applied during release of units.

Donations that are found unsuitable for transfusion should be autoclaved, discarded and incinerated or stored for research purposes. All discarded units should be documented and taken out of inventory.

Considerations shall be given to the need for extended storage of unused expired CP, to make them available for research purposes. Unused or expired units meant for research purposes should be stored separately. Documentation should show the destination of such units.

Transportation of blood components

The CP units should be transported in appropriately validated cold boxes in temperature-controlled conditions according to standard operating procedures.

Note: All blood specimens must be treated as potentially hazardous and, therefore, handled with standard protocol and use of the appropriate PPEs.

3. Guidance on transfusion of convalescent whole blood or plasma

3.1 Selection of COVID-19 patients

Convalescent plasma (CP) has a potential role in treating COVID-19 patients by providing antibodies to SARS-CoV-2, the virus that causes COVID-19. A few limited studies suggest that CP may be both safe and effective therapy. However, the prescribing clinician must
be mindful of the residual risks of transfusing any blood products, including acute immunological transfusion reactions, fluid overload, acute lung injury and transfusion transmissible viral infections. Therefore, the potential benefits of administering CP must outweigh the risks.

Convalescent plasma must be used only for patients meeting the following criteria:

1. COVID-19 infection confirmed by RT-PCR with either
2. Features of severe COVID-19, defined as one or more of the following:
   a. Dyspnoea
   b. Respiratory rate ≥ 30 cycles/min
   c. Blood oxygen saturation ≤ 93%
   d. >50% lung infiltrates within 24 to 48 hours
   OR
3. Features of life-threatening COVID-19 disease, defined as one or more of the following:
   a. Respiratory failure/Acute Respiratory Distress Syndrome (ARDS)
   b. Sepsis/Septic shock
   c. Multi-organ dysfunction or failure

3.2 Informed consent
As with the administration of any blood component for transfusion, the attending physician must obtain informed consent from the patient prior to administration. The reason for the transfusion, the expected outcomes, alternative therapies, and risks of transfusion must be clearly communicated to the patient and documented. A standardised informed consent/refusal of consent has been provided to facilitate this purpose. (Appendix 3)

Where a patient is unable to give consent e.g. patient is a minor or unconscious, the physician must obtain written consent from the patient’s authorized representative or guardian (in the case of minors).

Refusal of consent to receive convalescent plasma should not be construed as refusal to receive other medical intervention.

3.3 Collection of patient’s blood samples for laboratory testing
A blood request form must be fully completed by the physician, and must include details on the patient identity, type of blood component (i.e. “COVID-19 convalescent plasma”), and the number of units required.
Two venous 5ml blood samples should be collected: one sample into EDTA tube for ABO and RhD grouping, antibody screening, and crossmatching and a second sample into a plain tube for baseline SARS-CoV-2 antibody titres.

Patients must verbally confirm their identity at sampling. Unconscious patients may have their identity confirmed against identifiers on wristband by two clinical staff. Sample tube labels must be handwritten AFTER sampling, and contain the first and last names and age/date of birth of the patient, hospital number, ward, date and time of sampling.

For plasma transfusion, the EDTA blood sample is required to confirm ABO and RhD grouping, but not for crossmatching, and may be omitted if the blood bank has previously confirmed the patient’s blood group. However, the request form must be fully completed. The completed request form and patient’s sample must be delivered as soon as possible to the blood bank.

3.4 Selection of convalescent plasma units for transfusion
Convalescent plasma units selected for transfusion must be ABO-compatible with the recipient (RhD compatibility is not relevant). Units must be thawed at the blood bank in a controlled temperature system before issue. If not immediately required, thawed plasma may be stored for up to 24 hours at 2-4°C before transfusion.

<table>
<thead>
<tr>
<th>Patient’s ABO Blood Group</th>
<th>Compatible ABO Blood Group of Plasma for Transfusion</th>
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<tbody>
<tr>
<td>O</td>
<td>O or A or B or AB</td>
</tr>
<tr>
<td>A</td>
<td>A or AB</td>
</tr>
<tr>
<td>B</td>
<td>B or AB</td>
</tr>
<tr>
<td>AB</td>
<td>AB (A if AB not available)</td>
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3.5 Administration of convalescent plasma
Plasma must be administered by a trained doctor or nurse.

Prior to transfusion, the following must be checked at the patient’s bedside:

(1) The patient’s stated first and last names, date of birth or age and hospital number must be identical on both the patient’s wrist band (or ward documents) and the Blood Compatibility Label affixed to the plasma unit (or the accompanying Blood Compatibility Form).
(2) The ABO and RhD blood group on the Blood Compatibility Label and the Blood Pack Label must be identical.

(3) The plasma unit must be without visible physical defects, including leakage at ports and seams, blood clots and haemolysis, and must not contain clots, cellular aggregates or fibrin strands.

In adult patients, convalescent plasma should be administered in up to 2 doses of 250ml units each, transfused 12 hours apart. For patients with multi-organ failure one dose of 200-250ml may be considered, with the patient closely monitored for volume overload. For paediatric transfusions, a dose of 10ml/kg is recommended.

It is not necessary to warm thawed plasma prior to transfusion.

A record of the transfusion must be entered into the patient’s clinical records or a transfusion record form (Appendix 7). Details must include (1) Type of Blood Product (2) the Donation Number (3) ABO & RhD Group (4) Baseline vital signs (5) Date and Time of start of transfusion (6) Rate of Transfusion (7) Date and Time of completion of the Transfusion (8) Unexpected events occurring during the transfusion.

CP must not be co-administered with intravenous (IV) drugs or fluids through the same intravenous line. Where IV drug administration is urgent, the transfusion should be temporarily stopped and the IV line flushed with normal saline before and after the IV administration of the drug.

3.6 Patient monitoring
Patients receiving plasma must be observed continuously throughout the transfusion. Vital signs: (1) temperature, (2) blood pressure, (3) pulse, (4) respiratory rate and (5) oxygen saturation, must be recorded at the following points:

- Not more than 30 minutes prior to transfusion
- Every 15 minutes after start of the transfusion
- On completion or stopping the transfusion
- Hourly after the end of transfusion until 24 hours post transfusion.

The rate of administration of the transfusion must be monitored to ensure that plasma is administered at a rate of 10ml/min and completed within 4 hours.

A fluid input-output chart must be recorded for all patients who are candidates for plasma transfusion.

In the event of an acute transfusion reaction (typically manifested as new or worsening fever, dyspnoea, hypo- or hypertension, hypoxia, or allergic signs), the transfusion must
be stopped and appropriately managed by the attending physician according to national guidelines. Any suspected acute transfusion reaction, including mild forms, must be reported to the blood bank using the Transfusion Reaction Reporting Form (Appendix 9). Where required, appropriate samples must be sent to the blood bank for further investigation. For suspected haemolytic transfusion reactions, blood and urine samples must be sent to the general laboratory for further investigation.

During and after the transfusion, up to 24 hours post-transfusion, any unexpected symptom or sign manifesting must be documented in the Transfusion Reaction Reporting Form (Appendix 9) and a copy sent to the blood bank.

All used blood bags and blood administration lines, regardless of the outcome of the transfusion, must be returned to the blood bank, to facilitate further investigation in the event of a delayed transfusion reaction and for eventual safe disposal.

The results of the investigation of confirmed transfusion reactions following transfusion of convalescent plasma should be documented and reported to the clinical team for inclusion in the clinical notes, the Haemovigilance Unit of the NBS/Blood Centre, and the Food & Drugs Authority.

*Post Transfusion Laboratory Monitoring*

A 5ml sample should be collected in a plain tube after 48hours post-transfusion of convalescent plasma, and subsequently repeated every 48 hours till full recovery, to measure antibody titres to SARS-CoV-2. SARS-CoV-2 RNA levels should be assayed by RT-PCR every 2 days following transfusion of convalescent plasma.

On discharge, all recipients of convalescent plasma must be provided written guidance for reporting any unexpected symptoms or signs.

4. Other considerations

There should be the capacity to support these interventions. This includes adequate human resources and critical supplies, infection control procedures in place, as well as the ability to collect, analyse and interpret data.
4.1 Human resource and supplies of critical materials

The NBS will work with the MOH and GHS to ensure that appropriate levels of equipment, consumables and trained staff are available in the approved facilities for safe blood collection from patients recovered from COVID-19, and for testing and adequate storage and transportation of COVID-19 CWB/CP.

4.2 Infection control

The handling of blood samples from patients with COVID-19 for blood grouping and cross-matching by the hospital blood bank or laboratory personnel, should be done in accordance with specific infection prevention and control guidelines. Any serum/plasma samples being archived for future testing should also be handled and stored in a similar manner. Standard safety precautions should be followed for the handling of blood and plasma donations and samples from COVID-19 CP donors.

4.3 Data collection, analysis and interpretation

Information on a minimum number of data elements for donors and patients should be collected using a Data Collection Form (Appendix 4) primarily for health statistics purposes and also for the assessment of patients’ response, without compromising the urgency of the treatment. In order to assess the value of this treatment intervention, it is important to gather data on patient outcome with respect to their COVID-19 infection. Data collection, analysis and interpretation will be coordinated by the NBS.
5. References


6. Appendices

6.1 Convalescent plasma collection workflow

Figure 1: Convalescent plasma collections workflow (adapted from Bloch et al 2020)

**History of COVID-19: Patient database**
- Diagnosis of SARS-CoV-2 infection/COVID-19:
- Positive test for SARS-CoV-2 RNA or Antibody using FDA approved assays

≥14 days following resolution of symptoms

**Pre-donation screening: Clinical provider**
- Clinical assessment: no sign of active infection (i.e. afebrile, no reported symptoms for ≥14 days)
- Negative result for SARS-CoV-2 by nasopharyngeal (NP) swab/ Nasal Aspirate / molecular testing of blood
- Collection of two blood samples of 5ml each (one in EDTA and one serum separator tube) for anti-SARS-CoV-2

**Molecular testing** (using an FDA approved test)
- Testing of NP swab/ Nasal Aspirate for SARS-CoV-2 RNA, at least 7 days after first negative test

**Antibody testing** (using an FDA approved tests)
- ELISA for total Anti-SARS-CoV-2
- Anti-SARS-CoV-2 Neutralizing antibodies

**Negative NP swab for SARS-CoV-2 RNA**
Sero-positive total anti-SARS-CoV-2; anti-SARS-CoV-2 neutralizing antibodies >1:80

**Collections/processing: Blood Centre**

Criteria for donation
- Satisfies **ALL eligibility criteria** for blood donation based on NBS pre-donation medical assessment

Collections
- 450-600mL (apheresis) 200 - 250mLs (processed from whole blood) plasma (frozen within 24hrs of collection)
- Labeled; quarantine pending results of standard TTI testing
- Routine donation testing

**Transfusion: ABO compatible**
- Meet criteria for patient qualification
- Written informed consent, should explain risks of convalescent plasma e.g.
  - Transfusion Related Acute Lung Injury (TRALI)
  - Antibody Dependent Enhancement (ADE)
  - Transmission of SARS-CoV-2 (thrombosis)

**Monitoring:**
- Serious adverse events of transfusion
- Antibody titers to SARS-CoV-2:
  - baseline, days 1,3,7,14
- SARS-CoV-2 RNA by RT-PCR:
  - baseline, days 1,3,7,14
- Time until negative SARS-CoV-2 RT-PCR
6.2 Consent form for the donation of COVID-19 convalescent whole blood (CWB) or COVID-19 plasma

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 a disease caused by a virus which is primarily transmitted between people through respiratory droplets and contact routes. The disease can be mild, moderate or severe, depending on a number of factors.

Except for some experimental treatments, no proven treatment or vaccine is currently available to treat or prevent COVID-19. Only a few primary prevention measures have been established focusing on avoiding contact with droplets from an infected person and contaminated surfaces, and improved personal 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. We think 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 proven treatment options at present, we would like to try it in case it is successful, as it has been for certain other viruses with some success. 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) Testing your blood**
   If you agree to donate some blood or plasma for the treatment of COVID-19, we will ask you to come to the blood donation centre and we will first take a small amount of your blood (about 10ml), about a tablespoonful, from a vein in your arm using a single use sterile syringe and needle and do some tests that will tell us the type of blood that you have and also whether your blood can be used for treatment of COVID-19. If the amount of haemoglobin is too low or if your blood has the possibility of causing disease in another person, or you are not able to donate due to some other reason, we will not be able to accept your blood donation. If that happens, we will explain to you in detail the reasons why your blood cannot be taken, and if you need to have any medical treatment. If, however, you are suitable to donate, we will arrange a suitable time for the donation.

   **b) Collection and storage of blood or plasma units**
   For the donation, we will ask you to come to the blood donation facility, where you will be given something to drink (water or juice) before the donation of blood or the liquid part of your blood (plasma). Donating blood is very simple. The nurse/doctor will then ask you to lie on a couch or clinic bed. The inner area of one of your elbows will be cleaned with an antiseptic solution before a trained health worker inserts a sterile needle, connected to a blood bag, into your vein. The volume of blood taken will be about 350ml - 450ml (This is a little less than the volume of a sachet water which is 500ml). It usually takes only about 10 minutes to donate a unit of blood.

   If you are donating the plasma on a special machine, a trained health worker will put a small needle into a vein in your arm, through a sterile single use needle. 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 trained health worker will collect about half a litre (e.g. small mineral water bottle) of plasma. This procedure will take about 45-60 minutes.

   You will be given light refreshments after the procedure. 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 24 - 48 hours.
c) What happens next?
The blood that has been collected will be separated into plasma and red cells and stored in a freezer with an identification number. If plasma has been collected it will also be stored in a freezer. It will not have your name on it. The remaining red cells may or may not be used. When there is a patient who is likely to benefit from the use of plasma donated by you, it will be taken out from storage, and 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. We will take all preventive measures to minimize these risks. Some people may feel light-headed or little giddy, especially while donating plasma. This lasts for only a few minutes and quickly subsides.

4. Confidentiality
Any information that you provide and all your 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 COVID-19 would receive your blood. It is difficult to predict who exactly will receive the blood that you donate. The person must have a compatible blood type to yours. Your name will not be on the blood or plasma you have donated; it will just be identified with a unique donation number. So no one will know whose blood is being given to the patient. And you will not know who receives it either. But 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. no-one, including the person who receives your blood, will know who has provided the blood. This is so that your privacy can be protected.

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. You will however be reimbursed for the direct cost of transportation to and from the donation site.

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 informed by the doctor in charge.

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 attending doctor.

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 decline to donate, or request the discard of your blood or plasma, if it has not been transfused, will not affect your future care.

9. **Who to contact if you have any questions**
If you have any questions, feel free to contact us at the blood centre ..................

Please sign below to document your permission for the donation.

<table>
<thead>
<tr>
<th>Signature of Donor:</th>
<th>Full Name:</th>
<th>Date of Signature:</th>
</tr>
</thead>
<tbody>
<tr>
<td>x__________________</td>
<td>x__________________</td>
<td><strong><strong>/</strong></strong>/____</td>
</tr>
</tbody>
</table>

_
6.3 Consent form for treatment with COVID-19 convalescent whole blood (CWB) or COVID-19 plasma therapy

National Blood Service Ghana

Consent Form for Treatment with COVID-19 Convalescent Plasma

Therapy for [Insert Patient Name] .................................................................

You / Your ward* / Your family member* have/has* been diagnosed with severe COVID-19 illness. Currently there is no definite treatment for the condition; however, a number of therapies have been found useful and are part of patient care.

You are being offered the choice of COVID-19 convalescent plasma as part of the treatment. This document is to explain what this treatment is, the risks and benefits, the patient’s rights, so that you can make an informed decision.

What is Convalescent Plasma?
People who have recovered from the disease have substances known as ANTIBODIES in their blood that can attack the virus. Convalescent plasma is a product made from blood rich in antibodies, and which is donated by people who have recovered from the disease. Reports from other countries suggest that convalescent plasma can lessen the severity of the illness or shorten its duration. However, at present, we do not have strong evidence on how effective this treatment is, or whether it makes a difference.

What are the risks of receiving this treatment?
COVID-19 is not known to be transmitted through transfusion of blood or its components. We believe the risk of contracting a new infection through transfusion is very low, because the convalescent plasma has been sourced from donors who have fully recovered and have twice tested negative for the virus that causes COVID-19.

In general, blood and plasma are very safe and only compatible plasma will be used for transfusion. However, every blood product carries risks that include, but are not limited to, allergic reactions, fever, blood incompatibility or, rarely, death.

The National Blood Service has carefully tested the convalescent plasma for agents that cause HIV, hepatitis B, hepatitis C and syphilis. However, as with any other blood product, there remains a small risk of exposure to these and other infections that can be transmitted through blood or its components, although this risk is remote.

What are the benefits of receiving this treatment?
Evidence from other similar coronavirus illnesses show that antibodies against viruses boosts one’s ability to recover from the illness. However, we are unable to absolutely guarantee that convalescent plasma will increase the antibodies to COVID-19 or provide any other benefit. We expect to learn more about the usefulness of this treatment in COVID-19 as more people receive this treatment.

What are your rights?
You can choose whether or not this treatment should be given. If you choose to go ahead with the treatment, you are absolutely free to change your mind and withdraw at any time. Your choice will not affect the care being given at this centre.

Any information on the use of this treatment is part of the patient medical records and will be kept confidential. Data that is used and shared by specialists to better understand COVID-19 and its potential treatments will not include information by which patients can be personally identified.

If you have questions or concerns about treatment with convalescent plasma or medical problems, you are free to talk to your doctor.

I have understood the information given me about using convalescent COVID-19 plasma as part of treatment.

Therefore, I ☐ CONSENT ☐ DO NOT CONSENT
to the use of COVID-19 convalescent plasma as part of this treatment.

Name of Patient*

Name of Guardian/Next of Kin [For Incapacitated Adult Patients]*

Signature of Patient/Guardian/Next of Kin* ______________________ Date ____________

I, the undersigned, have fully explained the relevant information of this treatment to the patient named above.

Physician Name

Physician Signature ______________________ Date ____________

Witnessed by:

Witness Name & Signature ______________________ Date ____________

* delete as appropriate
6.4 Data Collection Form: Treatment with COVID-19 convalescent COVID-19 plasma transfusion (CP)

<table>
<thead>
<tr>
<th>DONATION RECORD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Donation Number</td>
</tr>
<tr>
<td>Copy of Completed Donor Clinical Record Attached?</td>
</tr>
<tr>
<td>Donor Information</td>
</tr>
<tr>
<td>Sex:</td>
</tr>
<tr>
<td>Pregnancy History?</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>COVID-19 Diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date:</td>
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<tr>
<td>Symptoms:</td>
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<td></td>
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<table>
<thead>
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<tbody>
<tr>
<td>Test 1</td>
</tr>
<tr>
<td>Date:</td>
</tr>
<tr>
<td>Batch No:</td>
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<tr>
<td>Laboratory:</td>
</tr>
<tr>
<td>Result:</td>
</tr>
<tr>
<td>Test 2</td>
</tr>
<tr>
<td>Date:</td>
</tr>
<tr>
<td>Batch No:</td>
</tr>
<tr>
<td>Laboratory:</td>
</tr>
<tr>
<td>Result:</td>
</tr>
</tbody>
</table>

<table>
<thead>
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<th>Blood Collection</th>
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<tbody>
<tr>
<td>Date:</td>
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<tr>
<td>Time:</td>
</tr>
<tr>
<td>Collection Method:</td>
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<tr>
<td>Site of Collection:</td>
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<table>
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<tr>
<th>LABORATORY RECORD</th>
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</thead>
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<tr>
<td>Processing Centre</td>
</tr>
<tr>
<td>Date:</td>
</tr>
<tr>
<td>Time:</td>
</tr>
<tr>
<td>Plasma Separation</td>
</tr>
<tr>
<td>Date:</td>
</tr>
<tr>
<td>Time:</td>
</tr>
<tr>
<td>Routine Test Results</td>
</tr>
<tr>
<td>HIV-1 &amp; 2:</td>
</tr>
<tr>
<td>HBsAg:</td>
</tr>
<tr>
<td>HCV Ab:</td>
</tr>
<tr>
<td>TPHA:</td>
</tr>
<tr>
<td>SARS-CoV-2 Antibody Testing</td>
</tr>
<tr>
<td>Test Batch Number:</td>
</tr>
<tr>
<td>Test Date:</td>
</tr>
<tr>
<td>Antibody Titres:</td>
</tr>
<tr>
<td>Other Tests</td>
</tr>
<tr>
<td>Units Prepared</td>
</tr>
<tr>
<td>Component Type:</td>
</tr>
<tr>
<td>Vol:</td>
</tr>
<tr>
<td>Date Issued:</td>
</tr>
<tr>
<td>Destination:</td>
</tr>
<tr>
<td>Component Type:</td>
</tr>
<tr>
<td>Vol:</td>
</tr>
<tr>
<td>Date Issued:</td>
</tr>
<tr>
<td>Destination:</td>
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# COVID-19 Convalescent Plasma Therapy

## Patient Information

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<thead>
<tr>
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<tbody>
<tr>
<td>Patient Name</td>
<td></td>
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<tr>
<td>Date of Birth</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td>☐ Male ☐ Female</td>
</tr>
<tr>
<td>Hospital</td>
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</tr>
<tr>
<td>Ward</td>
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### COVID-19 Diagnosis

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Date Diagnosed</td>
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<tr>
<td>Severity</td>
<td>☐ Mild  ☐ Pneumonia ☐ Severe</td>
</tr>
<tr>
<td>Complication</td>
<td>☐ ARDS ☐ Sepsis ☐ Septic Shock</td>
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### Blood Bank Record

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<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABO &amp; Rh (D)</td>
<td></td>
</tr>
<tr>
<td>Irreg. Antibodies</td>
<td></td>
</tr>
<tr>
<td>Most recent Transfusion</td>
<td></td>
</tr>
<tr>
<td>Component</td>
<td></td>
</tr>
<tr>
<td>Date</td>
<td></td>
</tr>
<tr>
<td>Previous Convalescent Therapy?</td>
<td>☐ Yes ☐ No</td>
</tr>
<tr>
<td>Date</td>
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## Transfusion Record

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<tr>
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</thead>
<tbody>
<tr>
<td>Date Requested</td>
<td></td>
</tr>
<tr>
<td>Time Requested</td>
<td></td>
</tr>
<tr>
<td>Consent Signed</td>
<td>☐ Yes ☐ No</td>
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<tr>
<td>Attending Physician</td>
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### Component Details

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</thead>
<tbody>
<tr>
<td>Component Type</td>
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<tr>
<td>Donation Number</td>
<td></td>
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<tr>
<td>Expiry Date</td>
<td></td>
</tr>
<tr>
<td>Volume</td>
<td></td>
</tr>
<tr>
<td>ABO &amp; Rh(D)</td>
<td></td>
</tr>
<tr>
<td>Date of Issue</td>
<td></td>
</tr>
<tr>
<td>Time of Issue</td>
<td></td>
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</table>

### Monitoring Record

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<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Transfusion Checks?</td>
<td>☐ Yes ☐ No</td>
</tr>
<tr>
<td>Time Started:</td>
<td></td>
</tr>
<tr>
<td>Time Stopped:</td>
<td></td>
</tr>
<tr>
<td>Time</td>
<td>BP</td>
</tr>
<tr>
<td>Pre-Tx</td>
<td></td>
</tr>
<tr>
<td>15 mins</td>
<td></td>
</tr>
<tr>
<td>1 hour</td>
<td></td>
</tr>
<tr>
<td>2 hour</td>
<td></td>
</tr>
<tr>
<td>Stop</td>
<td></td>
</tr>
<tr>
<td>4hrs Post</td>
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</table>

### Outcome

<table>
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<tbody>
<tr>
<td>Uneventful</td>
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</tr>
<tr>
<td>Stopped o/a</td>
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</tr>
<tr>
<td>Reaction</td>
<td></td>
</tr>
<tr>
<td>IV Access</td>
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<tr>
<td>Other</td>
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## Outcome

### Sample Collection Dates

<table>
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</thead>
<tbody>
<tr>
<td>Baseline</td>
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</tr>
<tr>
<td>Day 3</td>
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</tr>
<tr>
<td>Day 5</td>
<td></td>
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<tr>
<td>Day 7</td>
<td></td>
</tr>
<tr>
<td>Day 14</td>
<td></td>
</tr>
<tr>
<td>Clinical Outcome</td>
<td></td>
</tr>
<tr>
<td>Recovered, Discharged</td>
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</tr>
<tr>
<td>Died, Date of Death</td>
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</tbody>
</table>

### Patient Ab Titres:

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>SARS-CoV-2 RNA Levels</td>
<td></td>
</tr>
</tbody>
</table>
6.5 Protocol on Post-Donation Care

POST-DONATION CARE

COVID-19 Convalescent Plasma or Whole Blood Donors give their time and blood voluntarily and selflessly to provide for the care of others. The safety and welfare of blood donors demonstrates appreciation for this noble act, and is therefore a critical function of the National Blood Service, and in particular, its donor care staff. In addition, adequate support for the blood donor before, during and after the blood donation process will facilitate donor retention, and improved availability of convalescent plasma for therapy.

The Blood Centre must therefore ensure that trained staff, resources (e.g. operating manuals, information leaflets etc.) are available to see to the post-donation support and care for blood donors. The ultimate responsibility for post-donation care lies with the Head of the Blood Centre, but may be delegated to appropriately resourced staff in donor care.

This protocol for Post-Donation Care of COVID-19 Convalescent Plasma or Whole Blood Donors is condensed from the NBS Blood Donor Selection and Care Manual, which serves as the reference document for the post-donation care of blood donors.

A. Post-Donation Education of the Donor

Every blood donor must be provided information verbally and in writing on the following:

1. The need to boost iron levels in their body after blood donation with daily iron-rich foods, together with Vitamin C-rich fruits and vegetables. This is important if the donor gave whole blood as a source for convalescent plasma, rather than plasma-only donation by apheresis.
2. The need to increase their intake of oral fluids after blood donation for the next 24 hours.
3. Prevention of bruising of the arm at the venepuncture site by avoiding lifting heavy objects for a few days, and first-aid relief with cold compress or paracetamol for mild bruising, and danger signs requiring further assessment by a nurse or physician.
4. First aid in the event they feel dizzy or have cold sweats, including sitting or lying down, raising feet, loosening clothes, taking long breaths.
5. First aid in the event of fresh bleeding from the venepuncture site on removing the plaster, which includes applying gentle pressure, raising the arm for a few minutes and applying bandage for a few hours.
6. The need to contact the National Blood Service if they have reason to believe that the blood they have donated may not be suitable for transfusing to a patient, or if they would like to change any information provided on the donor questionnaire.
7. The need to contact the National Blood Service if they develop difficulty breathing, generalised weakness, fever, cough, loss of loss of taste or smell or any other feeling of illness within 2 weeks of donating blood.
8. The need to contact the National Blood Service if they develop yellow eyes, unexplained weight loss, or a cough persisting for more than four weeks, within 3 months of donating blood.

All Donors must be provided a copy of the NBS blood educational leaflet “Frequently Asked Questions”, and the contact number of the Blood Centre must be highlighted.

B. Follow Up of Donor Complications

Adverse events associated with blood donation include localised injuries such as haematoma or nerve irritation, and generalised reactions such as vasovagal reactions. An adverse blood donation reaction may be observed by Blood Centre staff during the blood donation activity, or may be reported later to the Blood Centre staff. Donors who give plasma by apheresis procedure may rarely experience a citrate reaction in which temporary hypocalcaemia from anticoagulant infusion leads to features of hypocalcaemia, including peripheral neurological deficits.

The NBS protocols for follow-up of donation complications should be followed. Based on the description of the symptoms or signs, the donor care staff should provide appropriate advice, with reference to recommendations in the Blood Donor Selection and Care Manual. The Donor Care nurse should discuss all cases that do not meet case descriptions with a Medical Officer at the Blood Centre.

Donors should be followed up by phone until complications are resolved. In some cases, photographs of localised lesions may be shared and are helpful to monitor progress. The Donor Care team should arrange personal visits for donors who are hospitalized or have severe complications.

All reports of donor reactions or incidents should be documented in the appropriate haemovigilance records (Blood Donor Incident Form, Session Report etc.).

C. Reactive Test Result for Transfusion-Transmissible Infection (TTI)

Before donating blood, donors should be informed of the tests that will be performed on their blood, and that they can expect communication from Blood Centre staff on test results. The donor must give written consent to these prior to donating blood.

Post-donation counselling for TTI is intended to give clients correct information and advice to enable them to deal with the health and social issues that may arise from the results of a blood test.

The counselling must be provided with utmost confidentiality and empathy for the donor, with particular regard to their autonomy and self-respect.

Where a blood donor’s sample is confirmed reactive for a transfusion-transmissible infection such as Hepatitis B or C, or HIV, the NBS protocol on post-donation counselling for TTI reactivity must be followed.
1. The donor must be contacted to arrange an appointment for post-donation counselling, either by calling in to the Blood Centre, or by a home visit by a trained counsellor.
2. The donor must be informed of the result and given a copy of the test report. The counsellor must allow the donor to ask questions, and to ensure that the donor understands the result. Immediate concerns must be addressed, and the donor should be encouraged to suggest a close person who may offer support.
3. A follow-up visit at an appropriate and accessible health facility where the donor can receive treatment, care and support should be discussed.
4. The counsellor should provide information on healthy lifestyle, good nutrition and how to prevent further transmission of the infection.
5. The counsellor should discuss how, when and to whom the donor would choose to disclose the result. The counsellor should encourage and offer referral for testing and counselling of partners and children.
6. Finally, the counsellor should agree with the donor on a specific date and facility for referral for treatment, care, counselling and other support, and provide the donor a written referral for that purpose.

D. Lookback Procedures

If a recipient of convalescent plasma seroconverts for markers of transfusion-transmissible infection for which the transfusion of convalescent plasma is implicated as the source of the infection, a lookback investigation must be carried out.

1. All transfused blood components must be identified from the patient records, and archived samples retrieved for re-testing.
2. All donors, including the convalescent plasma or whole blood donor, must be recalled for counselling and testing of fresh samples.
3. The donors must be counselled on the test results according to the TTI post-donation counselling guidelines.
4. The lookback report must be shared with the recipient’s doctor, the Haemovigilance Office, and the Food & Drugs Authority.

If a convalescent plasma or whole blood donor who was previously negative for TTI markers subsequently tests positive or reports new information to the Blood Centre implicating possible TTI exposure, a lookback investigation is similarly warranted. All potentially infectious donations must be identified and archived samples re-tested. Where archived samples show false negative results, the testing methods will have to be validated. Convalescent plasma may be stored for up to a year, and therefore all blood components prepared from implicated donations must be identified, and their fate documented. Recipient blood banks must be notified, in order to identify the fate of the component at the hospital, including recipient details. Recipients of convalescent plasma must be notified and tested for the relevant markers.
All reports of lookback investigations should be documented in the appropriate haemovigilance records (Blood Donor Incident Form, Session Report etc.).
6.6 Protocol on Post-Transfusion Care

POST-TRANSFUSION CARE

In the event of an acute transfusion reaction (typically manifested as new or worsening fever, dyspnoea, hypo- or hypertension, hypoxia, or allergic signs), the transfusion must be stopped and appropriately managed by the attending physician according to national guidelines. Any suspected acute transfusion reaction, including mild forms, must be reported to the blood bank using the Transfusion Reaction Reporting Form. Where required, appropriate samples must be sent to the blood bank for further investigation. For suspected haemolytic transfusion reactions, blood and urine samples must be sent to the general laboratory for further investigation.

During and after the transfusion, up to 24 hours post-transfusion, any unexpected symptom or sign manifesting must be documented in a Transfusion Reaction Reporting Form and a copy sent to the blood bank.

All used blood bags and blood administration lines, regardless of the outcome of the transfusion, must be returned to the blood bank, to facilitate further investigation in the event of a delayed transfusion reaction and for eventual safe disposal.

*Post Transfusion Laboratory Monitoring*

A 5ml sample should be collected in a plain tube every 2 days post-transfusion of convalescent whole blood or plasma to measure antibody titres to SARS-CoV-2. SARS-CoV-2 RNA levels should be assayed by RT-PCR every 2 days following transfusion of convalescent plasma.

On discharge, all recipients of convalescent plasma must be provided written guidance for reporting any unexpected symptoms or signs.

The results of the investigation of confirmed transfusion reactions following transfusion of convalescent plasma must be documented and reported to the clinical team for inclusion in the clinical notes, the Haemovigilance Unit of the NBS/Blood Centre, and the Food & Drugs Authority.
Transfusion Record Form A (ver. 2)

Please complete ALL sections of this form fully. If Not Applicable, write N/A in the relevant section.

SECTION I – PATIENT INFORMATION
Surname: ___________________________
First Name: ___________________________
Patient ID/NHS: ___________________________
Hospital: ___________________________
Department: ___________________________
Ward: ___________________________

Gender: ☐ Male ☐ Female ☐ not stated
AGE OF PATIENT: __________
Pre-Transfusion: Hb: __________
Plat: __________

Patient’s ABO/RhD Group: ☐ O ☐ A ☐ B ☐ AB ☐ + RhD ☐ - RhD
RhD: ☐ Unknown

Diagnosis: ___________________________
Component Type: ☐ Whole Blood ☐ CRK ☐ Hct: Random ☐ Platelet: Apheresis ☐ FFP ☐ Oryo ☐ Other: ___________________________
Attribute of Component: ☐ Mismatch PRF

SECTION II – RECORD OF TRANSFUSION
Donation No (Batch No): __________
Expiry date of unit: __________
Transfused Unit ABO/RhD Group: ☐ Unknown
Any previous Transfusions? ☐ Yes ☐ No
Rh: ☐+ RhD ☐ - RhD ☐ Unknown

Numbers of units/episodes transfused within Current admission/treatment cycle
NAME cross-checked pre-transfusion? ☐ Yes
ABO/Rh cross-checked pre-transfusion? ☐ Yes
Donation # cross-checked pre-transfusion? ☐ Yes

Record of Vital Signs: Please tick against fever, calsitation, hypo/hypertension under signs and symptoms when abnormal values are recorded

<table>
<thead>
<tr>
<th>Time</th>
<th>Pulse</th>
<th>Resp. Rate</th>
<th>Blood Pressure Systolic</th>
<th>Blood Pressure Diastolic</th>
<th>Temp</th>
<th>Oxygen Saturation Levels (SpO2)</th>
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</thead>
<tbody>
<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30-60 minutes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

At Finish or Stop

Were there any challenges completing this transfusion?
☐ NO
☐ YES, what was the Volume Transfused: __________ ml
        Stop Date: __________ Stop Time: __________

If YES: What were the challenges?
☐ Challenges with venous access
☐ Clots/Poor blood flow/Hyper viscous unit
☐ Other Reason (Please State) __________

Was there a transfusion reaction? ☐ YES ☐ NO

SECTION III – TRANSFUSION REACTION REPORTING

During Transfusion: ☐ 0-15 mins ☐ 15-30 mins ☐ 30 mins-1 hrs ☐ 1-2 hrs ☐ 2-4 hrs ☐ >4 hrs
Post Transfusion: ☐ <30 mins ☐ 30 mins-1 hrs ☐ 1-2 hrs ☐ 2-6 hrs ☐ 6-24 hrs ☐ >24 hrs

Specimens accompanying this form (kindly indicate)
☐ No sample
☐ 2ml patient’s blood sample (opposite arm) in EDTA tube
☐ 5ml patient’s blood sample (opposite arm) in plain tube
☐ 20ml urine (if applicable)
☐ All blood bags and unused units with attached giving set

Signs/Symptoms (tick as many apply)
☐ Itching/Pruritus
☐ Chills/Rigors
☐ Fever
☐ Nausea
☐ Rash/Urticaria
☐ Flushing and sweating
☐ Dyspnoea
☐ Chest pain / Tight chest
☐ Anxiety
☐ Restlessness
☐ Palpitations (pulse = __________ bpm)
☐ Hypotension (BP = __________ mmHg)
☐ Hypertension (BP = __________ mmHg)
☐ Back pain/flank pain/Loin pain
☐ Nausea
☐ Dark urine
☐ Unexplained bleeding
☐ Respiratory distress (hoarseing/stridor)
☐ Other: __________________________

Please tick a Suspected Adverse Reaction:
☐ Incorrect blood component transfused (IBCT)
☐ Acute Haemolytic transfusion reaction (IMMEDIATE)
☐ Delayed Haemolysis
☐ Delayed serologic reaction (DSTR)
☐ Febrile non-haemolytic transfusion reactions (FNHTR)
☐ Allergic reactions
☐ Septic Shock
☐ Transfusion related acute lung injury (TRALI)
☐ Transfusion –Associated Circulatory Overload (TACO)
☐ Transfusion associated Graft versus Host disease (GVHD)
☐ Post-Transfusion Purpura (PTP)
☐ Transfusion associated dyspepsia (TAD)
☐ Hypotensive transfusion reaction
☐ Haemosiderosis
☐ Hyperkalemia
☐ Unclassifiable Complication of Transfusions (UCT)

Suspected Severity:
☐ Grade 1 (non-severe)
☐ Grade 2 (severe)
☐ Grade 3 (life-threatening)
☐ Grade 4 (death)

*Grade 4 should be used only if death is possibly, probably or definitely related to transfusion. If the patient died of another cause, the severity of the reaction should be at grade 3 or 2.

Reporting Nurse: ___________________________
Contact Number: ___________________________
Date: ___________________________

Reporting Physician: ___________________________
Contact Number: ___________________________
Date: ___________________________
6.8 Transfusion Reaction Investigation Form

(Draft: ver. FEB 25, 2018)

Please return this form with samples and blood bags to Hospital Blood Bank as soon as possible.

**Transfusion Record Form B (ver. 2)**

Please complete ALL sections of this form fully. If Not Applicable, write N/A in the relevant section.

### SECTION IV – TRANSFUSION REACTION INVESTIGATION FORM

<table>
<thead>
<tr>
<th>Patient information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surname:</td>
</tr>
<tr>
<td>Patient ID/NHIS:</td>
</tr>
<tr>
<td>Hospital:</td>
</tr>
<tr>
<td>Gender: Male □ Female □</td>
</tr>
<tr>
<td>Ward:</td>
</tr>
</tbody>
</table>

### Investigation of Transfusion Reaction

<table>
<thead>
<tr>
<th>Name of Person Performing Test</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Donor’s ABO/RhD Group:</td>
<td></td>
</tr>
<tr>
<td>ABO: □ A □ O □ B □ AB □ Unknown</td>
<td></td>
</tr>
<tr>
<td>RhD: □ + RhD □ - RhD □ Unknown</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Clinical Checks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haemolysis</td>
</tr>
<tr>
<td>ABO</td>
</tr>
<tr>
<td>RhD</td>
</tr>
<tr>
<td>DAT</td>
</tr>
<tr>
<td>Antibody Screen</td>
</tr>
<tr>
<td>Antibody Identified</td>
</tr>
<tr>
<td>Anti-A, anti-B titre</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pre-Transfusion Sample</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Post-Transfusion Sample</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Donation/Batch No:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>ABO/RhD and Haemolysis Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haemolysis</td>
</tr>
<tr>
<td>IS</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cross-match PRE-Transfusion Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>IS</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cross-match POST-Transfusion Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>IS</td>
</tr>
</tbody>
</table>

### Verified Adverse Reaction: To be completed by Haemovigilance Officer

- Incorrect blood component transfused (IBCT)
- Acute Haemolytic transfusion reaction (Immediate)
- Delayed Haemolysis
- Delayed serologic reaction (DSR)
- Febrile non-haemolytic transfusion reactions (FNHTR)
- Allergic reactions
- Septic Shock
- Transfusion related acute lung injury (TRALI)

### Verified Severity*:

- Grade 1 (non-severe)
- Grade 2 (severe)
- Grade 3 (life-threatening)
- Grade 4 (death)

*Grade 4 should be used only if death is possibly, probably or definitely related to transfusion. If the patient died of another cause, the severity of the reaction should be as grade 1, 2 or 3.

### Imputability*:

- Definite
- Probable
- Possible
- Unlikely
- Excluded

*Only possible, probable and definite cases should be used for international comparisons.

### Transfusion Reaction Outcome: □ Complete Recovery □ Recovered with Complication □ Death

### Comments: ____________________________

### Haemovigilance Officer Signature

Date: ____________________________

---

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# Transfusion Reaction Reporting Form

Please complete ALL sections of this form fully. If Not Applicable, write N/A in the relevant section.

## PATIENT IDENTIFICATION
- **Surname:**
- **First Name:**
- **Hospital:**
- **Ward:**
- **Hospital #**
- **Age:**
- **Male**
- **Female**
- **Patient’s Blood Group:**

## TRANSFUSION INFORMATION
- **Diagnosis and Indication for Transfusion:**
- **Pre-Transfusion Hb:**
- **g/dL**
- **Blood Product:**
  - [ ] Whole Blood
  - [ ] Packed Red Cells
  - [ ] FFP
  - [ ] Platelet Concentrate
- **Unit Number:**
- **Blood Group of Unit:**
- **Volume transfused:**
- **ml.**
- **Date Transfusion started:**
- **Time Transfusion started:**
- **Date Reaction observed:**
- **Time Reaction observed:**
- **Unit Numbers transfused before reaction:**
- **Any Previous Transfusion?**
  - [ ] Yes
  - [ ] No
- **Any Previous Reaction?**
  - [ ] Yes
  - [ ] No

## SYMPTOMS (tick as many apply)
- **Itching**
- **Chills/Rigors**
- **Fever _____ °C**
- **Nausea**
- **Rash**
- **Urticaria**
- **Dyspnoea**
- **Chest pain / Tight chest**
- **Anxiety**
- **Restlessness**
- **Palpitations (pulse = ____ bpm)**
- **Hypertension (BP = __________ mmHg)**
- **Back/Flank pain**
- **Oliguria**
- **Dark urine**
- **Unexplained bleeding**
- **Other ________________**

## MANAGEMENT
- **Outcome:**
  - [ ] Complete Recovery
  - [ ] Recovered with Complication
  - [ ] Death
- **Specimens accompanying this form:**
  - [ ] 2ml patient's blood sample (opposite arm) in EDTA tube
  - [ ] 5ml patient's blood sample (opposite arm) in plain tube
  - [ ] 20ml urine (if applicable)
  - [ ] All blood bags and unused units with attached giving set

## Reporting Physician:
- **Date:**
- **Contact Number:**

Please return this form with samples and blood bags to Hospital Blood Bank as soon as possible.