LICENSING TERMS AND CONDITIONS ON

BLOOD TRANSFUSION

IMPOSED UNDER SECTION 6(2) (a) OR 6(5) OF THE PRIVATE HOSPITALS AND MEDICAL CLINICS ACT (CAP 248)

I Introduction

1 These licensing terms and conditions set out the requirements for the provision of blood transfusion services, which involve the transfusion of whole blood or one or more blood components listed in Annex A.

2 “Blood transfusion”, in the context of these licensing conditions, refers to the administration to a person by bolus injection or continuous infusion, whole blood or any blood component or product that is derived from the plasma, red blood cells, white blood cells and/or platelets of that person or one or more other persons.

3 Under the PHMC Regulations, blood transfusion services is considered a form of specialised/special care service in
   (a) private hospitals (Regulation 18, Second Schedule); and
   (b) medical clinics (Regulation 37, Third Schedule)
Licensees of hospitals and medical clinics are required to obtain prior approval from the Director of Medical Services under Regulation 18 and 37 respectively of the PHMC Regulations before commencing any blood transfusion service. Approval may be granted subject to compliance with these licensing terms and conditions, which are imposed under section 6(2) (a) or section 6(5) of the PHMC Act, whichever the case may be.

4 A licensee of a hospital or medical clinic who has been given prior approval referred to in paragraph 3 shall comply with these licensing terms and conditions. A breach of these licensing terms and conditions may attract potential consequences under the PHMC Act, including but not limited to:
   (a) Suspension or revocation of the approval to provide blood transfusion services;
   (b) Suspension or revocation of hospital licence or medical clinic licence;
   (c) Prosecution.

II Provision of blood transfusion services

5 No medical clinic shall provide any blood transfusion services. The exceptions are:
(a) Ambulatory surgery centres; and
(b) Specialist clinics managed by hematologists/ oncologists that carry out elective blood transfusions as part of the clinical management of patients with hematological conditions and/or cancers.

Any elective blood transfusion shall only be carried out under the supervision of a hematologist or medical oncologist who is registered with the Singapore Medical Council.

6 No person or healthcare institution shall process, administer or transfuse any blood or blood component as part of aesthetic practice or for any indication that is poorly supported by scientific evidence.

7 There shall be ready access to adequate resuscitation and monitoring facilities to deal with any emergency or complication arising from blood transfusions.

III Quality Assurance

8 The Licensee shall establish a Quality Assurance Programme, which shall be reviewed annually.

9 The Licensee of the healthcare institution shall appoint a committee under the Quality Assurance Programme to oversee the quality of any blood transfusion service that is provided. The committee shall function in accordance with “THE ROLE OF THE INSTITUTIONAL TRANSFUSION COMMITTEE” set out in Annex B. The chairperson of the committee shall be any specialist registered with the Singapore Medical Council in anaesthesiology, paediatric medicine or any internal medicine-based specialty, and shall have at least five years of experience in managing patients requiring transfusion as a specialist.

10 There shall be a framework for receiving, evaluating, investigating, documenting and reporting errors, adverse events and accidents relating to all blood transfusion services.

11 A report of the quality assurance activities regarding blood transfusion services shall be submitted to the Director of Medical Services at such time and in such form as the Director shall require.

IV Equipment & Supplies

12 All equipment for the purpose of blood transfusion shall be certified/licensed as safe or in good working condition by the relevant authorities or agencies.

13 Where applicable, blood transfusion equipment shall be scheduled for regular maintenance (including preventive maintenance), monitoring and
calibration according to manufacturers’ recommendations. Records must be made available for licensing inspection.

V Documentation

14 The Licensee shall ensure that documentation in relation to blood services is properly kept and secured. The documentation shall include the following at the minimum:

Facility, staff and equipment

(a) Job descriptions, qualification(s) and training records of personnel administering the blood transfusion;
(b) Preventive maintenance, monitoring and calibration records of equipment necessary for blood transfusion (if any).

Procedure

(c) Policies and records on administering blood transfusion, including assessment and verification of the identity of the recipient prior to blood transfusion;
(d) Policies and records on infection control and disposal of contaminated waste;
(e) Records on internal audits on blood transfusion for tracing units of blood transfused to patients;
(f) Policies on the management of blood transfusion reactions.

Recipient

(g) Types and incidence of adverse events, near misses and errors related to transfusion;
(h) Clinical management of recipients who suffer adverse events from blood transfusion, if any;
(i) Peer-review of adverse events, near misses and errors related to blood transfusion;
(j) Actions taken to address areas of deficiencies, if any.

15 Written policies and SOPs on blood transfusion shall be maintained, regularly reviewed and made available to all staff.
LIST OF BLOOD COMPONENT DESCRIPTIONS

Cryoprecipitated Antihemophilic Factor
The cold insoluble portion of plasma processed from Fresh Frozen Plasma.

Cryoprecipitated Antihemophilic Factor, Pooled
Two or more units of Cryoprecipitated Antihemophilic Factor combined into one bag. The total volume will be indicated on the label. To assist in the pooling process, 0.9% sodium chloride (USP) may be added.

Fresh Frozen Plasma
Plasma separated from the blood of an individual donor and placed at -18°C or colder within 6 to 8 hours of collection from the donor, depending upon the anticoagulant or collection device.

Granulocytes Pheresis (a.k.a Apheresis Granulocytes)
A suspension of granulocytes in plasma prepared by cytapheresis.

Granulocytes/Platelets Pheresis (a.k.a Apheresis Granulocytes/ Platelets)
A suspension of granulocytes in plasma prepared by cytapheresis, with the concurrent collection of platelets.

Irradiated Blood Components
Blood or blood component that has been exposed to gamma irradiation to prevent proliferation of T lymphocytes. Includes the following:
- Granulocytes Pheresis, Irradiated
- Granulocytes/Platelets Pheresis, Irradiated
- Platelets, Irradiated
- Platelets Pooled, Irradiated
- Platelets Pheresis, Irradiated
- Platelets Pheresis, Leukocytes Reduced, Irradiated
- Red Blood Cells, Irradiated
- Red Blood Cells Leukocytes Reduced, Irradiated
- Red Blood Cells Pheresis, Irradiated
- Whole Blood, Irradiated

Liquid Plasma
Plasma separated from the blood of an individual donor and not frozen.

Plasma Cryoprecipitate Reduced
Fresh Frozen Plasma from which cryoprecipitate has been removed.

Plasma for Manufacture (a.k.a Recovered Plasma)
Plasma for use in manufacturing and prepared from allogeneic donations. Plasma selected for manufacture that has been collected from whole blood or apheresis plasma collected for transfusion that has expired (non commercial plasma derived products).
Plasma Frozen Within 24 Hours of Collection
Plasma separated from the blood of an individual whole blood donor and placed at -18°C or colder within 24 hours of the collection.

Platelets
A suspension of platelets in plasma prepared by centrifugation of whole blood.

Platelets Pooled
Two or more units of platelets that have been combined into one bag.

Platelets Leukocytes Reduced
Platelets Leukocytes Reduced are prepared by a method known to reduce the leukocyte number to < 8.3 × 10^5 in at least 95% of the components sampled.

Platelets Leukocytes Reduced Pooled
A suspension of platelets in plasma that has been leukocyte reduced. The leukocyte reduction process can take place either before or after the pooling process.

Platelets Pheresis
A suspension of platelets in plasma prepared by cytapheresis. Whole Blood undergoes centrifugation in a cell separator, with the return to the donor of components not collected.

Platelets Pheresis Leukocytes Reduced
Platelets collected by apheresis that are prepared by a method known to reduce the residual leukocyte number to < 5 × 10^6 in 95% of the components sampled.

Red Blood Cells
Red cells concentrated by the removal of most of the plasma from sedimented or centrifuged whole blood.

Red Blood Cells Deglycerolized
Red blood cells to which glycerol has been added (eg. as a cryoprotective agent) and subsequently removed by washing with successively lower concentrations of sodium chloride (USP).

Red Blood Cells Frozen
Red Blood Cells that have been stored in the frozen state at optimal temperatures in the presence of a cryoprotective agent.

Red Blood Cells Leukocytes Reduced
Red Blood Cells prepared by a method known to retain at least 85% of the original red cells and to reduce the leukocyte number in the final component to < 5 × 10^6.
Red Blood Cells Low Volume
When 300-404 mL of whole blood is collected into an anticoagulant volume calculated for 450 +/- 45 mL or 333-449 mL of whole blood is collected into an anticoagulant volume calculated for 500 +/- 50 mL of whole blood.

Red Blood Cells Pheresis
Red Blood Cells in anticoagulant or in anticoagulant and storage solution that have been prepared by automated cytapheresis.

Red Blood Cells Pheresis Leukocytes Reduced
Red Blood Cells in anticoagulant or in anticoagulant and storage solution that have been prepared by automated cytapheresis that have been leukocyte reduced by a method known to retain at least 85% of the original red cells and to reduce the leukocyte number in the final component to < 5 \times 10^6.

Red Blood Cells Rejuvenated
Red Blood Cells that have had 2,3-diphosphoglycerate and adenosine triphosphate restored to normal levels or above.

Red Blood Cells Rejuvenated Deglycerolized
Red Blood Cells that have had 2,3-diphosphoglycerate and adenosine triphosphate restored to normal levels or above, subjected to a cryoprotective agent and stored frozen at optimal temperatures. The cryoprotective agent is subsequently removed by washing with successively lower concentrations of sodium chloride (USP).

Red Blood Cells Rejuvenated Frozen
Red Blood Cells that have had 2,3-diphosphoglycerate and adenosine triphosphate restored to normal levels or above and then subsequently exposed to a cryoprotective agent and stored at optimal temperatures in a frozen state.

Red Blood Cells Washed
Red Blood Cells remaining after washing with a volume of compatible solution using a method known to remove almost all of the plasma. Depending on the method used, the preparation may contain variable quantities of leukocytes and platelets from the original unit.

Thawed Plasma
Thawed plasma prepared from Fresh Frozen Plasma or Plasma Frozen within 24 Hours of Collection, that has been thawed and stored for up to 5 days.

Thawed Plasma Cryoprecipitate Reduced
Thawed plasma prepared from Plasma Cryoprecipitate Reduced.

Whole Blood
Whole Blood is collected in an anticoagulant/ preservative solution and is not further processed. This product should not be used as a source of platelets or labile coagulation factors.
ANNEX B

THE ROLE OF THE INSTITUTIONAL TRANSFUSION COMMITTEE

Organisation

This Committee should comprise the following members:
(a) the officer in charge of the healthcare institution’s transfusion services;
(b) clinical representatives of departments in the healthcare institution that carry out blood transfusions; and
(c) members of nursing staff.

Functions of the Committee

(a) Develop and implement institutional guidelines for the transfusion of blood and blood components;
(b) Carry out audits on blood transfusion practices;
(c) Investigate undesirable effects of transfusion and, where necessary, institute corrective measures;
(d) Promote continuing education in transfusion medicine for institutional staff;
(e) Assist the Blood Services Group (HSA) and Singapore Red Cross Society in blood procurement efforts, where appropriate.