LICENCE CONDITIONS FOR

LICENSEES PROVIDING OR INTENDING TO PROVIDE BLOOD TRANSFUSION SERVICE

IMPOSED UNDER SECTION 13(1) OF THE HEALTHCARE SERVICES ACT 2020

1 Application

1.1. These licence conditions ("**LCs**") apply to:

(1) all persons that have been licensed under the Healthcare Services Act 2020 (the "**HCSA**") to provide:

(a) an acute hospital service ("**AHS**");
(b) an ambulatory surgical centre service ("**ASCS**");
(c) an outpatient medical service ("**OMS**"); and/or
(d) a community hospital service ("**CHS**"); and

(2) that provide or intend to provide, as part of the aforementioned service or services, Blood Transfusion Service (as defined in paragraph 2.1(4) below),

(such persons referred to as "**Licensees**").

1.2 For avoidance of doubt,

(a) the defined terms as used in these LCs shall have the meaning ascribed to them in the HCSA and any Regulations made thereunder, unless otherwise stated; and

(b) the requirements in these LCs are without prejudice, and in addition to the requirements imposed under the HCSA as well as any Regulations and other applicable licensing conditions, directions, codes of practice made thereunder.

1.3 A breach of these LCs may result in regulatory action being taken against Licensees under section 20 of the HCSA, including but not limited to:

(a) suspension or revocation of the Licensee's licence(s) to provide AHS, ASCS, OMS and/or CHS;
(b) shortening the term of the Licensee's licence(s) to provide AHS, ASCS, OMS and/or CHS;
(c) a direction requiring the Licensee to rectify the contravention, or prevent a recurrence of the contravention; and/or
(d) a direction requiring the Licensee to pay a financial penalty.

2 Definitions

2.1 The following definitions shall apply to these LCs:

(1) "**autologous donation**" refers to the donation of blood and blood component by a donor for his/her own use.

(2) "**blood component**" includes plasma, red blood cells, white blood cells, platelets and cryoprecipitate.

(3) "**blood product**" refers to any product derived from plasma, red blood cells, white blood cells or platelets.

(4) "**blood transfusion service**" or "**BTS"** means —
- (a) the collection of whole blood, or blood component or product that is derived from plasma, red blood cells, white blood cells or platelets from an individual for the purpose of administering it to that individual (as a patient) or another patient;
- (b) the administration to a patient, by bolus injection or continuous infusion, of either or both of the following, whether obtained from the patient or one or more other individuals:
  - i. whole blood;
  - ii. any blood component or product that is derived from plasma, red blood cells, white blood cells or platelets; and
- (c) the temporary storage of any whole blood, or blood component or product that is derived from plasma, red blood cells, white blood cells or platelets for the purpose mentioned in paragraph (a) or (b).

(5) "**Clinical Nurse Leader"** means an individual who:
- (a) has been a registered nurse for at least 5 years; and
- (b) has at least 5 years of work experience in Singapore in —
  - i. transfusion medicine in –
    - (A) in relation to the provision of an AHS by a person authorised by a licence under HCSA to provide that licensable healthcare service; or
    - (B) in any private hospital licensed under the Private Hospitals and Medical Clinics Act 1980 (the "PHMCA"), where the private hospital is licensed as a medical hospital, a surgical hospital or both; or
  - ii. any other area relevant to the provision of a blood banking service with a licensee.

(6) "**directed donation**" refers to the donation of blood and blood component by a donor for the specific purposes of transfusion to a named patient.

(7) "**donor**" means an individual who donates blood or any blood component.

(8) "**medical practitioner**" means an individual who is registered under the Medical Registration Act 1997 (the "**MRA**") as a medical practitioner and holds a valid practising certificate under that Act.

(9) "**registered nurse**" means an individual who:

(a) is registered under the Nurses and Midwives Act 1999 (the "**NWA**") as a registered nurse; and
(b) holds a valid practising certificate that is issued under the NWA to practise as a registered nurse.

(10) "**specialist**" means a medical practitioner who is registered as a specialist in the Register of Specialists under section 22 of the MRA.

(11) "**transfusion**" refers to the administration to an individual 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 individual or one or more other individuals.

3 Specific Restrictions

3.1 Only Licensees holding AHS licenses as described in paragraph 1.1(1)(a) shall provide services relating to whole blood collection and blood components collection for the purposes of autologous donation and directed donation, within the licensed premises of an AHS.

3.2 Licensees holding ASCS licenses as described in paragraph 1.1(1)(b) shall not provide BTS, save for when a patient is in a medical emergency, within the licensed premises of an ASCS.

4 Requirements Relating to Personnel

4.1 All Licensees (save for Licensees holding AHS licenses and who provide services stipulated at paragraph 3.1 above) shall appoint one medical practitioner who:

(a) is a Specialist in the branch of anaesthesiology, haematology, paediatric medicine or other relevant internal medicine-based specialties[1]; and

(b) has at least 5 years of work experience in Singapore in –
i. transfusion medicine in –
(A) in relation to the provision of an AHS by a person authorised by a licence under HCSA to provide that licensable healthcare service; or

[1] These specialties include, but is not limited to, Cardiology, Intensive Care Medicine, Emergency Medicine, Endocrinology, Gastroenterology, Geriatric Medicine, Infectious Diseases, Medical Oncology, Neurology, Rehabilitation Medicine, Renal Medicine, Respiratory Medicine, Rheumatology.

(B) in any private hospital licensed under the PHMCA, where the private hospital is licensed as a medical hospital, a surgical hospital or both; or

ii. any other area relevant to the provision of a blood banking service with a licensee,

to be responsible for the clinical and technical matters relating to BTS.

4.2 Licensees holding AHS licences and who services stipulated at paragraph 3.1 above shall appoint one medical practitioner who:

(a) is a Specialist in the branch of haematology; and

(b) has at least 5 years of work experience in Singapore in –

i. transfusion medicine –

(A) in relation to the provision of an AHS by a person authorised by a licence under HCSA to provide that licensable healthcare service; or

(B) in any private hospital licensed under the PHMCA, where the private hospital is licensed as a medical hospital, a surgical hospital or both; or

ii. any other area relevant to the provision of a blood banking service with a licensee,

to be responsible for the clinical and technical matters relating to autologous and directed donation of blood and blood components.

5 Quality Management System

5.1 The Licensee shall:

(a) establish and maintain an effective quality management system ("**QMS**") for all aspects of the BTS relating to –

i. the safety and welfare of patients receiving the blood, blood component and/or blood product via transfusion;

ii. the safety and quality of the blood, blood component and/or blood product administered by the Licensee via transfusion;

(b) conduct annual reviews and internal audits on the policies, processes or procedures of the QMS; and

(c) make and maintain accurate reports of all reviews mentioned in sub-paragraph (b) to ensure the continuing suitability and effectiveness of the QMS.

5.2 Without limiting paragraph 5.1(a), the QMS shall provide for all of the following:

(a) the development, implementation and regular review of the policies and procedures relating to BTS, including but not limited to the following:

i. phlebotomy for pre-transfusion testing;

ii. requests for blood, blood component and/or blood product;
iii. handling, storage and transportation of blood, blood component and/or blood product;
iv. administration of transfusion and the monitoring of patients undergoing transfusion; and
v. identification, escalation and management of transfusion reactions;

(b) the implementation of safe transfusion practices (such as for emergency transfusion);

(c) the implementation of criteria for the safe and appropriate use of blood, blood component and/or blood product;

(d) the implementation of measures to monitor blood, blood component and/or blood product usage;

(e) the implementation of measures to minimise blood, blood component and/or blood product wastage;

(f) the implementation of measures to monitor transfusion reactions and other transfusion-related serious adverse events;

(g) the implementation of risk-mitigating measures to detect and address, in a timely manner, clinical or quality risks that affect:
i. the safety and welfare of patients; and
ii. the safety and quality of the blood, blood component and/or blood product;

(h) the implementation of an escalation process for notification errors, adverse reactions and near misses in the transfusion process;

(i) the implementation and regular review of the procedures relating to the appropriate corrective and preventive actions to be taken for errors, adverse reactions and near misses in the transfusion process; and

(j) the training of all personnel in, and assessment of their competence to implement any updated or revised policies, processes or procedures for the provision of BTS.

5.3 The Licensee shall appoint a blood transfusion committee ("**BTC**") to oversee the establishment and maintenance of an effective QMS, which shall comprise the following members:

(a) the medical practitioner referred to in paragraph 4.1 or 4.2 above, as the case may be;

(b) the clinical representatives of relevant departments that carry out blood transfusion for the Licensee; and

(c) members of the Licensee's nursing staff.

6 Premises, Equipment and Supplies

6.1 The Licensee shall ensure that the approved permanent premises and equipment for the storage and transport of blood, blood component and blood product, are appropriate and adequate for the maintenance of the stability, safety and quality of all blood, blood component and blood product, to be used for the blood transfusion activities conducted or to be conducted by the Licensee.

6.2 The Licensee shall ensure that, where applicable, equipment used for blood transfusion activities be scheduled for regular maintenance (including preventive maintenance), monitored and calibrated according to the relevant equipment manufacturers' specifications.

6.3 The Licensee shall ensure that all blood storage equipment is monitored continuously, or at least once every 4 hours ("**monitoring interval**"), to ensure that temperature is maintained consistently throughout the blood storage equipment.

6.4 The Licensee shall ensure that the shipping containers used for the transportation of blood, blood component and blood product shall be of sturdy construction and validated to maintain the appropriate temperatures of the blood, blood component and blood product for the period of transportation from a licensee described in paragraph 7.1(a) to 7.1(c), as the case may be, to the time of administering blood transfusion, in accordance with the requirements set out in **Annex A**.

6.5 The Licensee shall ensure that all materials that come into contact with any blood, blood component and blood product used for the provision of BTS are single-use, sterile and free of pyrogen.

7 Blood Transfusion Practices

7.1 The Licensee shall ensure that it only accepts blood, blood component and/or blood product for transfusion from persons that have been licensed under the HCSA to provide the following services:

(a) blood banking service(s);
(b) AHS; and
(c) clinical laboratory service(s) approved to provide transfusion medicine as part of that service(s).

7.2 The Licensee shall ensure that each request for transfusion of blood, blood component and/or blood product made by a medical practitioner explicitly states the identity of the patient for whom the request for transfusion is made.

7.3 Save for in emergency situations where (1) the patient has no mental capacity to consent to transfusion and (2) the medical practitioner attending to the

patient concludes that it is in the patient's best interests to undergo a transfusion, the Licensee shall obtain express informed written consent from the patient, or if the patient is a minor, from that patient's parent or legal guardian, before any planned transfusion. For avoidance of doubt, informed consent is only obtained if the patient or if the patient's parent or legal guardian (as the case may be) was informed of the risks, benefits and alternatives to blood transfusion.

7.4 The Licensee shall ensure that each transfusion of blood, blood component and/or blood product is only administered to a patient:

(a) upon prescription by a medical practitioner; and
(b) administered by a medical practitioner or registered nurse trained and assessed to be competent by the Licensee in administering transfusion.

7.5 The Licensee shall ensure that transfusion is administered to the patient without undue delay upon arrival of the blood, blood component and/or blood product to the patient's bedside.

7.6 Before transfusion is administered, the Licensee shall ensure that the blood, blood component and/or blood product satisfy all of the following requirements:

(a) the blood, blood component and/or blood product are of normal appearance (i.e. there is no presence of haemolysis and/or clots);

(b) the port or seal of the blood bag is intact (i.e. the integrity of the blood bag is not compromised); and

(c) the blood, blood component and/or blood product had been maintained at the appropriate temperatures and storage conditions for the period between the transportation from the refrigerators and/or freezers in which the blood, blood component and/or blood product was stored, to the time of administering blood transfusion.

7.7 The Licensee shall implement the following measures to ensure accurate identification of the patient at all stages of the BTS:

(a) prior to the transfusion, the personnel administering the transfusion and another personnel shall in the presence of the patient, verify the following information:
    (i) the patient's name and unique identification number ("**UIN**");
    (ii) the patient's ABO group and Rhesus type;
    (iii) the donor's ABO group and Rhesus type;
    (iv) the patient's prescription for blood transfusion; and
    (v) the patient's special transfusion requirement, if any.

(b) for the purposes of paragraph 7.7(a), in emergency situations, or in situations where the name and UIN of the patient cannot be immediately identified, the personnel administering the transfusion may assign a UIN to the patient, and identify that patient using that assigned UIN, and the patient's gender.

7.8 The Licensee shall ensure that the personnel administering the transfusion take the following steps to ensure that the blood administered to the patient is appropriate:

(a) the ABO blood group and Rhesus type on the blood bag matches the patient's blood group;

(b) the blood, blood component and/or blood product matches the patient's prescription;

(c) the blood, blood component and/or blood product had not passed its date of expiry;

(d) the blood bag shows no signs of damage, leakage, haemolysis or clots; and

(e) the blood, blood component and/or blood product complies with any special requirements, if applicable.

7.9 The Licensee shall ensure that patients receiving blood transfusion are continuously monitored and cared for, by taking the following steps:

(a) monitoring the vital signs of a patient and any potential adverse effects at intervals and for the length of time appropriate to the condition of the patient; and
(b) take appropriate steps to assess, identify and manage suspected adverse events including transfusion reactions.

7.10 In respect of situations where a patient who initially requires blood transfusion no longer requires the said transfusion:

(a) where the blood, blood component and/or blood product was obtained from a licensee described in paragraph 7.1(a) and 7.1(c):
    i. ensure that a process is put in place to return, as soon as practicable, any unused blood, blood component and/or blood product (collectively, the "**Unused Blood**") to the licensee described in paragraph 7.1(a) or 7.1(c), as the case may be; and
    ii. for the period between where the transfusion is deemed no longer required to the time of return of the Unused Blood to the licensee described in paragraph 7.1(a) or 7.1(c), ensure that there are adequate and effective measures to quarantine and prevent the inadvertent use of the Unused Blood; and

(b) where the blood, blood component and/or blood product was obtained from a licensee described in paragraph 7.1(b), ensure that there are adequate and effective measures to quarantine and prevent the inadvertent use of the Unused Blood.

8 Requirements for Licensees holding AHS licenses providing services relating to the collection of blood and blood components for the purposes of autologous donation and directed donation

8.1 The Licensee shall ensure that the collection of blood or blood components from donors for the purposes of autologous donation or directed donation is supervised by a medical practitioner or a Clinical Nurse Leader, who is physically present at all times while the collection is taking place.

8.2 The Licensee shall ensure that the medical practitioner or registered nurse performing the collection of blood or blood components from donors for the purposes of autologous donation or directed donation is competent in respect of all the following matters:

(a) the screening, selection and counselling of donors;
(b) the appropriate and timely monitoring and management of donors during the collection of blood and blood components;
(c) the clinical assessment of donors before, during and after the donation of blood and blood components; and
(d) the escalation for appropriate clinical management of incidents adversely affecting donors or any personnel involved in the recruitment and evaluation of donors or the collection of blood and blood components.

8.3 The Licensee shall ensure that the site of blood and blood component collection is set up to ensure the proper, safe and hygienic collection of blood and blood components from donors, and the privacy of the donors.

8.4 The Licensee shall:

(a) provide or arrange for the provision of pre-donation counselling to the donors by a qualified, trained and competent medical practitioner or registered nurse, in a manner that respects the donor's privacy; and

(b) conduct or arrange for the conduct of adequate and appropriate assessment of the donor's suitability to donate blood or blood components by a qualified, trained and competent medical practitioner or registered nurse.

8.5 The Licensee shall provide accurate and relevant information on all of the following matters to the donors in the course of pre-donation counselling and assessment of the donor's suitability mentioned in paragraph 8.2:

(a) the nature and use of blood and blood components and the importance of maintaining a healthy lifestyle as a blood donor;

(b) the importance of the donation of blood and blood components being voluntary and not being remunerated;

(c) the purpose of the donor questionnaire administered to and pre-donation health assessment of the donor, and the importance of providing truthful

responses and cooperating with the Licensee's measures to ensure the safety of all blood and blood components collected;

(d) that the donor may withdraw from or defer the donation of blood or blood components at any time, and the steps required by the donor to do so;

(e) that the donor should inform the Licensee if any blood and blood component donated is not safe for transfusion to another individual for any reason, and the steps required by the donor to do so;

(f) the donation process and possible adverse reactions that the donor may encounter;

(g) information on infectious diseases (as listed in the First Column of **Annex B**) that are transmissible by the transfusion of blood and blood components; and

(h) the steps that the Licensee may take in the event that any blood or blood component donated by the donor is found or suspected to be infected with any infectious disease mentioned in sub-paragraph (g).

8.6 The Licensee shall ensure that the collection of blood and blood components is carried out in a manner that ensures the traceability, safety and suitability for use of the blood or blood components collected, by taking the following actions:

(a) before collecting any blood or blood component from a donor, verify the identify of the donor using the donor's name and UIN;

(b) ensure that each unit of blood or blood component collected from the donor is labelled with the correct donation identification number at all times; and

(c) ensure that aseptic techniques are used during the collection of blood or blood components from the donor.

8.7 The Licensee shall, in relation to each donor, ensure that –

(a) the collection of blood or blood components from the donor is carried out in a manner that is safe and causes minimal discomfort to the donor; and

(b) the donor is adequately monitored and managed by one or more personnel after the collection of blood or blood components, and is discharged only when it is safe for the donor.

8.8 The Licensee shall ensure that appropriate processes are implemented to ensure a swift and appropriate response to any injury sustained by any donor, or any incident affecting the safety or health of any donor or any personnel that occurs, in the course of the collection of blood and blood components, including the rapid activation of emergency medical services.

8.9 The Licensee shall –

(a) test all donors for all specified infectious diseases listed in the First Column of **Annex B**, using the method stated in the corresponding row under the Second Column of **Annex B**; and

(b) ensure that each donor's specimen is tested by a licensee authorised to provide a clinical laboratory service, or a person who operates a clinical laboratory outside Singapore that is accredited by an accreditation body approved by the DGH, using a test or test method that is appropriate for blood donor testing, as specified by the manufacturer of the test kit.

8.10 Where any blood or blood component is found to be infected by a specified infectious disease listed in the First Column of **Annex B** or any other infectious disease that is likely to adversely affect the health of the donor of the blood or blood component, the Licensee shall inform the donor of that fact in a timely manner and provide the donor with appropriate information relating to the clinical follow-up for that infectious disease.

9 Documentation

9.1 The Licensee shall ensure that documentation in relation to each BTS provided is properly kept, secured, complete and accurate to ensure full traceability of blood, blood component and blood product, as the case may be, from the point of receipt or collection to the completion of blood transfusion. These documentation shall minimally include the following:

In relation to the facility, personnel and equipment:

(a) Job descriptions, qualification(s), training and competency records of personnel involved in the provision of BTS;
(b) Maintenance, monitoring, calibration and service records of equipment necessary for blood transfusion (if any);
(c) Records of the temperatures of the blood storage equipment at each monitoring interval;

In relation to the blood transfusion procedure:

(a) Records on administering blood transfusion, including assessment and verification of the identity of the patient prior to blood transfusion;
(b) Records on handling, storing and transportation of blood, blood component and/or blood product;
(c) Records on the management of patients' medical reactions to blood transfusion ;
(d) Records on internal audits on blood transfusion for tracing units of blood, blood component and blood product transfused to patient;

In relation to the donor

(h) Records of pre-donation counselling and donor assessment (including eligibility criteria and outcomes);

In relation to the patient receiving blood:

(i) Records of the types and incidence of adverse events, near misses or errors related to blood transfusion (collectively, "**Areas of Deficiencies**");
(j) Peer- review of the Areas of Deficiencies; and
(k) Actions taken to address the Areas of Deficiencies.

9.2 The Licensee shall ensure that all written policies and procedures be regularly maintained, reviewed and accessible to all personnel.

Annex A

REQUIREMENTS FOR THE STORAGE AND TRANSPORT OF BLOOD

Type of Blood	Requirements for the Storage of Blood	Requirements for the Transport of Blood
Whole Blood and Red Blood Cell Components	• Whole Blood and Red Blood Cell components shall be stored between 1°C and 6°C. • Blood shall be stored in a blood bank refrigerator which has been specially designed for the purpose. This includes blood that is kept in sites outside the blood bank, such as surgical or obstetric units. • Blood units shall be arranged so that the oldest blood is easily at hand and is used first.	• Whole Blood and all liquid Red Blood Cell components must be transported in sturdy, well-insulated containers with refrigerants that will ensure maintenance of a temperature of 1°C to 10°C. • Refrigerants used shall be adequate and appropriate to maintain temperature throughout the period of transportation and up to the time of administering transfusion. The recommended refrigerants are wet ice in leak-proof containers and chemical coolant pouches.
Fresh Frozen Plasma, Frozen Plasma and Cryoprecipitate	• Fresh Frozen Plasma, Frozen Plasma and Cryoprecipitate shall be stored at the temperature of -18°C or lower. • Stocks shall be rotated so that the oldest product is used first. • Fresh Frozen Plasma and Frozen Plasma which are thawed and used for the correction of labile coagulation factor deficiencies shall be transfused immediately. Thawed units of Fresh Frozen Plasma and Frozen Plasma shall not be re-frozen.	• Thawed Plasma must be transported in sturdy, well-insulated containers with refrigerant that will ensure maintenance of a temperature of 1°C to 10°C.

	• Fresh Frozen Plasma and Frozen Plasma shall be thawed between 30°C and 37°C, and stored at 1°C to 6°C for up to 24 hours. • Reconstituted cryoprecipitate shall be stored at room temperature until transfusion, and shall be administered within 6 hours of thawing, and 4 hours of pooling. Thawed units shall not be re-frozen.	
Platelets	• Platelet concentrates shall be stored at 20°C to 24°C. • Continuous gentle agitation is required. • If the hermetic seal of any bag containing platelets is broken, the platelets must be transfused within 4 hours.	• Platelets shall be maintained at temperatures of 20°C to 24°C during shipment. Well-insulated containers without added ice are sufficient.

Annex B

First Column: ***Specified Infectious Disease***	***Second Column:*** ***Test for the Specified Infectious Disease***
1. Human immunodeficiency virus (HIV) infection	(a) **Serology** (b) **Nucleic acid test**
2. Hepatitis B infection	(a) **Serology** (b) **Nucleic acid test**
3. Hepatitis C infection	(a) **Serology** (b) **Nucleic acid test**
4. Syphilis	(a) **Serology**