

LICENCE CONDITIONS FOR
HUMAN TISSUE BANKING SERVICE
IMPOSED UNDER SECTION 13(1) OF
THE HEALTHCARE SERVICES ACT 2020

1 Application

- 1.1. These licence conditions ("**LCs**") apply to all persons which have been licensed under the Healthcare Services Act 2020 (the "**HCSA**") to provide a human tissue banking service ("**HTBS**") (such persons referred to as "**Licensees**").
- 1.2. For avoidance of doubt, 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.
- 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 HTBS licence;
 - (b) shortening the term of the Licensee's HTBS licence;
 - (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.
- 1.4. For avoidance of doubt, these LCs do not override a medical practitioner's duty to exercise professional judgment and make clinical decisions that are in the best interests of each patient.
- 1.5. For avoidance of doubt, 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.

2 Qualifications, skills and competencies of Clinical Governance Officer (Regulation 7 of the Healthcare Services (Human Tissue Banking Service) Regulations 2023 ("HTBS Regulations"))

- 2.1. The Licensee shall ensure that its Clinical Governance Officer (as appointed under section 24(2) of the HCSA) has at least five years of work experience in providing a HTBS, blood banking or cord blood banking service¹.
- 2.2. The Licensee shall ensure that its Clinical Governance Officer delegates his or her duties to a suitably qualified personnel of its human tissue banking service ("**Bank**") only if:

¹ Acceptable work experience includes (i) setting up policies and procedures in relation to a HTBS, blood banking or cord blood banking service; (ii) assessing and establishing suitability criteria for specified human tissue, blood or cord blood intended for transplant or clinical use; (iii) supervision of staff; and (iv) reviewing quality assessment programmes.

- (a) the Licensee is satisfied with the Clinical Governance Officer's rationale for delegating his or her duties; and
 - (b) the Licensee is satisfied with the Clinical Governance Officer's assessment of the competency of that personnel in performing the Clinical Governance Officer's duties.
- 2.3. The Licensee shall retain all records, documents and information referred to in Clause 2.2 above, and shall ensure that such records, documents and information are available upon request by the Government.

3 Appointment of Advising Specialist (Regulation 8 of the HTBS Regulations)

- 3.1. Where the Licensee appoints a medical practitioner who is registered as a specialist in the branch of medicine relevant to the specified service (as defined under the First Schedule of the HTBS Regulations) that the Licensee is approved to provide for its Bank ("**Advising Specialist**"), the Licensee shall ensure that the Advising Specialist advises its Clinical Governance Officer(s) on the clinical aspects of that specified service. The Licensee shall ensure that the Advising Specialist's advice minimally covers:
- (a) the medical aspects of all handling, processing, testing, storage and distribution procedures of that specified service to be carried out for its Bank;
 - (b) the development of appropriate protocols for donor recruitment for its Bank, if the Licensee recruits donors; and
 - (c) the appropriate criteria to be utilised by the Licensee and the Clinical Governance Officer for the assessment of donor eligibility and the return of unused human tissue respectively.

4 General requirements relating to personnel (Regulation 9 of the HTBS Regulations)

- 4.1. The Licensee shall ensure that each personnel of its Bank, who is designated by the Licensee to explain information in relation to the donation of human tissue, attends annually at least one course or workshop or seminar related to medico-legal knowledge, family counselling, donor screening and assessment, or post-recovery process as part of the continuing training programme of its Bank's personnel.

5 Requirements relating to Premises (Regulation 11 of the HTBS Regulations)

- 5.1. The Licensee shall ensure that for the licensed premises of its Bank ("**Premises**"):
- (a) there are adequate environmental controls (such as temperature, humidity, and where applicable, pressure) for its Bank's personnel to carry out the human tissue banking service, and for the optimal functioning of equipment; and
 - (b) every part of the Premises which are used for the handling, processing, testing, storage and distribution of human tissue are regularly cleaned such that the safety of its Bank's personnel, and the safety and quality, and where applicable, viability and potency, of the human tissue will not be compromised.

6 Requirements relating to equipment and materials (Regulation 12 of the HTBS Regulation)

- 6.1. The Licensee shall ensure that for all of its Bank's temperature-dependent equipment:
- (a) temperatures of each of such equipment are measured, checked and recorded on each day of use;
 - (b) the temperatures recorded are traceable to each of such equipment; and
 - (c) all temperature measurements that fall outside of the acceptable limits shall be investigated and rectified in a timely manner.
- 6.2. The Licensee shall ensure that all temperature-monitoring devices in its Premises are verified against a reference standard or, in the case of reference thermometers, calibrated to a reference standard at least once every 12 months or as stated on the certificate of calibration.
- 6.3. The Licensee shall ensure that all biosafety cabinets and laminar airflow flow hoods in its Premises are cleaned before and after each use, and at regularly scheduled intervals to prevent cross contamination.

7 Evaluation and screening of donors (Regulation 17 of the HTBS Regulations)

- 7.1. The Licensee shall require all its Bank's donors of a type of human tissue, in relation to every infectious disease applicable to that type of human tissue as specified in the first column of the Second Schedule of the HTBS Regulations, to undergo all of the tests specified opposite that infectious disease in the second column of the Second Schedule.
- 7.2. The Licensee shall implement a testing algorithm to determine the presence of plasma dilution in all of its Bank's blood samples collected from all of its Bank's donors. The Licensee shall ensure that its testing algorithm is qualified for proper performance prior to its implementation and after any significant modifications to the testing algorithm.
- 7.3. Where plasma dilution is detected in a blood sample collected from a donor in its Bank, the Licensee shall as far as reasonably possible obtain from that donor a pre-transfusion or infusion blood sample ("**Pre-Transfusion Blood**") of sufficient quantity drawn up to 7 days before the collection of human tissue from that donor. The Licensee shall ensure that all of the necessary tests (as set out in the Second Schedule of the HTBS Regulations) are conducted on that donor's Pre-Transfusion Blood in accordance with Regulation 35 of the HTBS Regulations to assess whether that donor is eligible to donate human tissue.
- 7.4. The Licensee shall implement a policy in its Bank that minimally covers the process for:
- (a) the handling of blood samples collected from its Bank's donor; and
 - (b) the assessment of the eligibility of its Bank's donors for donation of human tissue,

wherein the Licensee is unable to determine the absence of plasma dilution.

8 Distribution of human tissue (Regulation 23 of the HTBS Regulations)

- 8.1. The Licensee shall ensure that all of its Bank's human tissue is identifiable and traceable, and the information accompanying human tissue during the distribution of human tissue is intact and complete.

9 Import of processed human tissue (Regulation 29 of the HTBS Regulations)

- 9.1. The Licensee shall ensure that any processed human tissue which is imported from a person outside Singapore must be:
- (a) imported from a person who is accredited by an accreditation body approved by the Director-General of Health in **Annex A**; or
 - (b) approved by its Clinical Governance Officer pursuant to Regulation 29(b) of the HTBS Regulations.

10 Tests on persons (Regulation 35 of the HTBS Regulations)

- 10.1. The Licensee shall ensure that any test on its Bank's donor which is conducted outside of Singapore must be conducted by a person who operates a clinical laboratory outside Singapore which is accredited by an accreditation body approved by the Director-General of Health in **Annex B**.

11 Outsourcing of tests on human tissue (Regulation 36 of the HTBS Regulations)

- 11.1. The Licensee may appoint a person to conduct, on the Licensee's behalf, a test of any of its Bank's collected human tissue that the Licensee considers necessary to ensure the safety and quality, and where applicable, the viability and potency, of that human tissue if that person operates a human tissue bank for the same type of human tissue or a clinical laboratory outside Singapore that is accredited by an accreditation body approved by the Director-General of Health in **Annex B**.
- 11.2. The Licensee shall ensure that where it appoints or engages another person to conduct a test on its behalf under Regulation 36(2) of the HTBS Regulations ("**Outsourced Person**"), the report of the Outsourced Person for that test is not copied or reproduced except in its entirety.

Annex A

LIST OF APPROVED ACCREDITATION BODIES FOR THE IMPORTATION OF HUMAN TISSUE FOR TRANSPLANTATION

The list of accreditation bodies approved by the Director-General of Health are as follows:

1. AABB (formerly American Association of Blood Banks)
2. American Association of Tissue Banks (AATB)
3. Eye Bank Association of America (EBAA)
4. Foundation for the Accreditation of Cellular Therapy (FACT)
5. Joint Accreditation Committee-ISCT & EBMT (JACIE)

Annex B

LIST OF APPROVED CLINICAL LABORATORY ACCREDITATION BODIES

The list of accreditation bodies approved by the Director-General of Health are as follows:

- (a) Accreditation Canada (Canada)
- (b) American Society for Histocompatibility and Immunogenetics (USA)
- (c) ANSI National Accreditation Board (ANAB) (USA)
- (d) Association for the Advancement of Blood & Biotherapies (AABB) (USA)
- (e) College of American Pathologists (USA)
- (f) Danish Accreditation (DANAK) (Denmark)
- (g) Deutsche Akkreditierungsstelle (DAkkS) (Germany)
- (h) Dutch Accreditation Council (Raad voor Accreditatie) (The Netherlands)
- (i) Foundation for the Accreditation of Cellular Therapy (USA)
- (j) International Accreditation New Zealand (New Zealand)
- (k) National Association of Medical Examiners (USA)
- (l) National Association of Testing Authorities (Australia)
- (m) National Pathology Accreditation Advisory Council (Australia)
- (n) Singapore Accreditation Council-Singapore Laboratory Accreditation Scheme (Singapore)
- (o) Swiss Accreditation Services (Switzerland)
- (p) Taiwan Accreditation Foundation (Taiwan)
- (q) The Joint Commission (USA) (formerly known as Joint Commission on Accreditation of Healthcare Organizations)
- (r) United Kingdom Accreditation Service (formerly known as Clinical Pathology Accreditation) (UK)