LICENCE CONDITIONS FOR

HUMAN TISSUE BANKING SERVICE LICENSEES PROVIDING OR INTENDING TO PROVIDE BANKING OF OCULAR TISSUE

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

1 Application

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

(a) licensed under the Healthcare Services Act 2020 (the "**HCSA**") to provide a Human Tissue Banking Service ("**HTBS**"); and

(b) providing or intending to provide the banking of ocular tissue.

(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, 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 Definitions

2.1. For the purposes of these LCs,

(a) "banking of ocular tissue" means the handling, processing, testing, storage and distribution of ocular tissue.

3 Collection of ocular tissue (Regulation 18 of the Healthcare Services (Human Tissue Banking Service) Regulations 2023 ("HTBS Regulations"))

3.1. Licensees shall ensure that ocular tissue is only collected by: -

(a) the enucleation; or

(b) the in-situ method.

3.2. Where ocular tissue is to be collected from the body of a deceased donor, the Licensees shall ensure that: -

(a) the collection of ocular tissue is completed as soon as possible after the death of the deceased donor, and within 24 hours of the death where practicable;

(b) the time interval between the deceased donor's time of death and the enucleation or excision of the ocular tissue for preservation, is recorded;

(c) the surface of the ocular tissue is exposed to antiseptic agent(s) at least once between the deceased donor's time of death and the enucleation or excision of the ocular tissue for preservation;

(d) the concentration and volume of antiseptic agent(s) and the duration of ocular surface exposure to the antiseptic agents(s) is expressly set out in the Licensee's written policies and procedures; and

(e) excess antiseptic agent(s) is irrigated from the ocular surface prior to its preservation.

4 Processing and preserving ocular tissue (Regulation 19 of HTBS Regulations)

4.1. Licensees shall ensure that only validated methods are used to process and preserve the ocular tissue, including but not limited to: -

(a) whole globe;

(b) cornea; and

(c) sclera.

5 Suitability of ocular tissue for distribution (Regulation 21 of HTBS Regulations)

5.1. Licensees shall: -

(a) establish parameters to determine the suitability of the ocular tissue to be distributed for each type of transplant; and

(b) ensure that the parameters established pursuant to paragraph 5.1(a) are aligned with industry standards, including but not limited to the standards set by the Eye Bank Association of America.

5.2. Licensees shall ensure that in determining the suitability of the ocular tissue pursuant to paragraph 5.1, each ocular tissue undergoes the following examinations and evaluation, where applicable: -

(a) **Gross examination**: An initial examination shall be conducted for a corneal-scleral segment for clarity, epithelial defects, foreign objects, contamination and scleral colour;

(b) **Slit-lamp examination**: After corneal excision and lamellar preparation of the corneal tissue, a corneoscleral disc shall be examined using slit lamp biomicroscopy for epithelial and stromal pathology, including but not limited to endothelial disease; and

(c) **Endothelial cell density and pachymetry examination**:

(i) a corneal tissue shall be examined using specular microscopy or quantitative light microscopy (where it is a cultured cornea) for endothelial cell density; and

(ii) after lamellar tissue preparation, a posterior lamellar graft shall be evaluated using pachymetry and cell density measurement.

5.3. The Clinical Governance Officer shall prescribe the minimal endothelial cell count limit for each type of transplant in the Licensee's written policies and procedures.

6 Specific requirements for corneal lenticule tissue

6.1. Licensees shall inform a corneal lenticule tissue donor (including a potential donor) that while there may be some scientific evidence supporting the clinical use of corneal lenticule tissue, there is no clinical or medical evidence of therapeutic use (potential or otherwise) for the corneal lenticule tissue.

6.2. Licensees shall ensure that each corneal lenticule tissue donor is: -

(a) informed of all material information on corneal lenticule tissue storage, and

(b) informed of the risk that there may not be a therapeutic use (potential or otherwise) for the stored corneal lenticule tissue.

6.3. Licensees shall ensure that compliance with paragraphs 6.1 and 6.2 is documented in writing.

6.4. Where preserved corneal lenticule tissue is issued for transplant or clinical use, Licensees shall ensure that:

(a) before the preserved corneal lenticule tissue is issued, there is sufficient clinical or medical evidence to substantiate the use of such corneal lenticule tissue for transplant or clinical use, and that such transplant or clinical use is accepted by Singapore's medical fraternity as the acceptable standard of care;

(b) the preserved corneal lenticule tissue is only issued for the purpose for which the donor of the corneal lenticule tissue has consented in writing; and

(c) the Director-General of Health is informed in writing of the intention to issue the preserved corneal lenticule tissue for transplant or clinical use, at least two (2) months prior to the date of the issuance.

7 Distribution of ocular tissue (Regulation 23 of HTBS Regulations)

7.1. Licensees shall ensure that preserved ocular tissue issued for transplant or clinical use, is issued in a validated container which is clearly and indelibly labelled with the information below:

(a) name of the ocular tissue bank or source of the ocular tissue;
(b) if the ocular tissue was collected from a deceased donor, the date and time of the donor's death;
(c) whether the cornea is pre-cut; and
(d) the date and time the ocular tissue was preserved.

7.2. Licensees shall ensure that preserved ocular tissue issued for transplant or clinical use: -

(a) is issued with a tissue report; and
(b) the tissue report includes the following information: -
    (i) name of the ocular tissue bank or source of the ocular tissue;
    (ii) if the preserved ocular tissue came from an ocular tissue bank, the location and contact number of the ocular tissue bank;
    (iii) unique identification number of the ocular tissue or fraction thereof;
    (iv) if the ocular tissue was collected from a deceased donor, the date and time of the donor's death;
    (v) the date and time the ocular tissue was preserved;
    (vi) the method of preservation used to preserve the ocular tissue, including the type of preservation medium;
    (vii) if the cornea is pre-cut, the indicated use for the cornea and the type of pre-cut method used, including but not limited to endothelial keratoplasty, posterior lamellar keratoplasty, anterior lamellar keratoplasty, laser assisted keratoplasty;
    (viii) the name of the person who collected, processed, and evaluated the preserved ocular tissue; and
    (ix) a summary of the records reviewed in assessing the eligibility of the preserved ocular tissue for transplant.
(c) the tissue report includes the following information, where applicable: -
    (i) estimated thickness and diameter of the ocular tissue;
    (ii) slit-lamp reports; and
    (iii) specular microscopy reports.

7.3. Licensees shall ensure that where possible, an expiration date is assigned to the preserved ocular tissue based on validated or proven methods of processing, preservation, storage, and packaging.