LICENCE CONDITIONS FOR

HUMAN TISSUE BANKING SERVICE LICENSEES PROVIDING OR INTENDING TO PROVIDE BANKING OF CARDIAC AND VASCULAR 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 cardiac and vascular 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 and codes of practice made thereunder.

2. Definitions

2.1. For the purposes of these LCs,

(a) "banking of cardiac and vascular tissue" means the handling, processing, testing, storage and distribution of cardiac and vascular tissue;

(b) **Warm Ischemic Time** – The time interval from asystole to subjecting cardiac or vascular tissue to cold rinse (or transport) solution during collection;

(c) **Cold Ischemic Time** – The time interval from subjecting cardiac or vascular tissue to cold rinse (or transport) solution during collection to the beginning of disinfection;

(d) **Total Ischemic Time** – The time interval from asystole to subjecting the cardiac or vascular tissue to disinfection solution. This is the sum of Warm Ischemic Time and Cold Ischemic Time and should not exceed 48 hours; and

(e) **Premises** – The premises at which the Licensee is licensed to provide the HTBS.

3. Collection of cardiac and vascular tissue (Regulation 18 of the Healthcare Services (Human Tissue Banking Service) Regulations 2023 ("HTBS Regulations"))

General requirements

3.1. The Licensee shall validate the time limits for post-mortem tissue collection.

3.2. The Licensee shall not exceed the following time limits for collection of the cardiac or vascular tissue:

(a) Warm Ischemic Time of 24 hours from asystole if the body was cooled or refrigerated within 12 hours of asystole; and

(b) Warm Ischemic Time of 15 hours if the body was not cooled or refrigerated within 12 hours of asystole.

(collectively referred to as "**Acceptable Time Limits**").

3.3. The Licensee shall treat the body referred to at paragraph 3.2 as one that was not cooled or refrigerated, if that body underwent a process of cooling or refrigeration which process was discontinued for a period of more than 15 cumulative hours.

3.4. The Licensee shall ensure that the cardiac or vascular tissue is transported to the Premises post-collection for processing at a temperature between above 0°C to 10°C that maintains the integrity of the cardiac or vascular tissue for its intended use.

3.5. The Licensee shall ensure that the cardiac or vascular tissue arrives at the Premises within the Acceptable Time Limits to allow for the start of disinfection within Cold Ischemic Time, such that the disinfection of the cardiac or vascular tissue does not exceed Total Ischemic Time.

3.6. The Licensee shall document the time that the cardiac or vascular tissue arrives at the Premises.

Specific requirements for cardiac tissue only

3.7. The Licensee shall ensure that the cardiac tissue is rinsed and packaged in an isotonic, sterile solution such as normal saline, lactated Ringer's solution, transplant organ perfusate, or tissue culture media, immediately following collection.

3.8. The Licensee shall ensure that the volume of the transport solution is adequate to cover the entire heart, including vessels and valves.

3.9. The Licensee shall document the type, lot number, manufacturer, and the expiration date of reagents used for collection and packaging.

Specific requirements for vascular tissue only

3.10. The Licensee shall ensure that perfusion time shall not exceed 24 hours from asystole provided that the vascular tissue is collected within the Acceptable Time Limits.

3.11. Immediately following collection, the Licensee shall ensure that vascular tissue is gently flushed and packaged in an isotonic sterile solution such as tissue culture media.

3.12. The Licensee shall document the type, lot number, manufacturer, and the expiration date of all reagents used for collection and packaging.

4. Processing, testing and quarantine of cardiac and vascular tissue (Regulation 19 of HTBS Regulations)

General requirements

4.1. The Licensee shall establish and implement a set of Standard Operating Procedures ("**SOP**") which shall include the following information:

(a) The desired processing temperatures at which the reagents are to be maintained when used for the processing of cardiac or vascular tissue;
(b) A standardised evaluation and classification system that describes the attributes of each allograft;
(c) A validated cold rate freezing method, where the cardiac or vascular tissue is to be cryopreserved. This shall include information on the rate of freezing, including a specified rate of freezing up to a predetermined end-point; and
(d) Validated appropriate protocols with respect to tissue integrity where the cardiac or vascular tissue is to be preserved otherwise than by cryopreservation.

4.2. The Licensee shall ensure that cardiac or vascular tissue is processed in a certified and qualified bacteriologically and climate-control environment, that is minimally ISO class 5 or equivalent.

4.3. The Licensee shall ensure that cardiac or vascular tissue is processed at the desired processing temperatures in accordance with the SOP set out at paragraph 4.1(a).

4.4. The Licensee shall ensure that the cardiac or vascular tissue shall be kept moist using sterile solution or medium, such as cold tissue culture media and cold saline, throughout processing except in the case where drying does not impact the integrity of the cardiac or vascular tissue for its intended use.

4.5. The Licensee shall ensure that a detailed description of the condition of the allograft is recorded in the processing records of the donor.

4.6. The Licensee shall ensure that, where the cardiac or vascular tissue is to be cryopreserved, the cardiac or vascular tissue is packaged with a cryoprotectant medium in accordance with the SOP set out at paragraph 4.1(c) above.

4.7. The Licensee shall ensure that, where the cardiac or vascular tissue is to be preserved otherwise than by cryopreservation, it is in compliance with the SOP set out at paragraph 4.1(d) above.

4.8. The duration from the completion of freezing to storage shall be minimised to ensure the integrity of the cardiac or vascular tissue. Temperature fluctuation shall be avoided during this transfer.

Specific requirements for cardiac tissue only

4.9. The Licensee shall maintain the temperature of cardiac tissue and solutions used at above 0°C to 10°C for cardiac tissue and solutions during heart dissection to prevent warm ischemia and potential cellular or matrix damage caused by temperature cycling.

4.10. The Licensee shall inspect, evaluate and size allograft heart valve grafts, by internal valve annulus diameter, and record in millimetres (mm). The length of the aortic conduit, main pulmonary artery, and the left and right pulmonary arteries shall be recorded in millimetres (mm) or centimetres (cm).

Specific requirements for vascular tissue only

4.11. The Licensee shall inspect, evaluate and size vascular tissue grafts by diameter and record in millimetres (mm). The length of the vascular segment shall be recorded in centimetres (cm).

5. Storage of cardiac and vascular tissue (Regulation 20 of HTBS Regulations)

5.1. The Licensee shall store processed cardiac or vascular tissue at -100°C or colder.

6. Suitability of cardiac and vascular tissue for distribution (Regulation 21 of HTBS Regulations)

6.1. The Licensee shall obtain appropriate final packaging cultures and ensure that the culture results meet established parameters defining the acceptability of final packaging cultures, before the cardiac or vascular tissue is distributed for transplantation.

7. Provision of information relating to cardiac and vascular tissue distributed for transplant (Regulation 25 of HTBS Regulations)

7.1. The Licensee shall make available the allograft evaluation system mentioned at paragraph 4.1(b) to the transplanting physician.

8. Return of cardiac and vascular tissue (Regulation 26 of HTBS Regulations)

8.1. The Licensee shall not return frozen or cryopreserved cardiac or vascular tissue to the tissue bank inventory after the said cardiac or vascular tissue has been thawed.

8.2. The Licensee shall not assign frozen or cryopreserved cardiac or vascular tissue for use to another patient where the final packaging has been opened.