

LICENCE CONDITIONS FOR
HUMAN TISSUE BANKING SERVICE LICENSEES
PROVIDING OR INTENDING TO PROVIDE
BANKING OF SKIN 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 skin 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 skin tissue" means the handling, processing, testing, storage and distribution of skin tissue.

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

- 3.1. The Licensee shall ensure that the collection of skin tissue is performed in a separate zone (i.e. a specific, well-defined area of the body that is separate from any other areas of the body where other tissue types may be collected) so that the culture results

relating to the skin tissue can be reviewed in isolation and without risk of contamination by other tissue types.

- 3.2. The Licensee shall not exceed the following time limits for skin preparation (i.e. the application of antiseptic solution to decontaminate the skin) during the collection of skin tissue:
 - (a) 24 hours from the time of asystole, in the case of a deceased donor whose body was cooled or refrigerated within 12 hours of asystole;
 - (b) 15 hours from the time of asystole, in the case of a deceased donor whose body was not cooled or refrigerated within 12 hours of asystole; and
 - (c) in considering whether (a) or (b) above is to apply, if the body underwent a process of cooling or refrigeration initially but that process was subsequently discontinued for more than 15 cumulative hours, the body is not to be considered “cooled” or “refrigerated” for the purposes of this section.
- 3.3. The Licensee shall ensure that the skin tissue is packaged in a sterile solution immediately following the collection of the skin tissue from the donor or packaged by another method that maintains the integrity of the skin tissue for its intended use.
- 3.4. Where the skin tissue is packaged in a sterile solution, the Licensee shall ensure that the volume of the sterile solution is adequate to cover the entire skin tissue for the whole duration it is required to be preserved for its intended use.
- 3.5. The Licensee shall document the type, lot number, manufacturer, and expiration date of the transport solution.
- 3.6. The Licensee shall ensure that the collected skin tissue is transported to the premises at which the Licensee is licensed to provide a HTBS for processing at a temperature between above 0°C to 10°C that maintains the integrity of the tissue for its intended use.
- 3.7. The Licensee shall document the time of acceptance of the skin tissue into the premises at which the Licensee is licensed to provide a HTBS.

4 Processing, testing and quarantine of skin tissue (Regulation 19 of HTBS Regulations)

- 4.1. Prior to processing the collected skin tissue, the Licensee shall perform a microbial culture of the skin tissue.
- 4.2. The Licensee shall ensure that inhibitory substances (e.g. skin preparation solution(s), transport media, antibiotics), that might have been added to the collected skin tissue either during the collection and/or transportation, do not interfere with the culture results (e.g. produce false negative results).
- 4.3. The Licensee shall ensure that the collected skin tissue is processed in a certified and qualified bacteriologically and climate-control environment, that is minimally ISO class 5 or equivalent.
- 4.4. The Licensee shall ensure that skin tissue is processed using aseptic techniques which involve the use of sterile instruments, consumables and materials.

- 4.5. The Licensee shall maintain the temperature of skin tissue and solutions used at above 10°C for no longer than 2 hours if additional warm ischemia and potential cellular or matrix damage caused by temperature cycling can impact the integrity of the skin tissue required for its intended use (e.g. skin tissue that is to be cryopreserved).
- 4.6. The licensee shall ensure that the processing of skin tissue that is to be frozen or cryopreserved is initiated within 10 days of collection of the skin tissue and provided that the skin tissue had been placed in tissue storage media that was replaced at least once every 72 hours. Where the tissue storage media was not replaced in that manner, the Licensee shall initiate the processing of skin tissue within 96 hours of collection of the skin tissue.
- 4.7. The Licensee shall ensure that the skin tissue is kept moist using sterile solution throughout the processing except in the case where drying does not impact the integrity of the skin tissue required for its intended use (e.g. decellularized dermis).
- 4.8. The Licensee shall ensure that where the skin tissue is to be cryopreserved, it is cryopreserved with a cryoprotectant medium. The skin tissue shall be frozen at a specific rate to a predetermined specific end-point. Where the skin tissue is to be preserved using other methods, the Licensee shall use protocols which the Licensee had validated would ensure the integrity of the skin tissue is maintained for its intended use.
- 4.9. Where the skin tissue is to be cryopreserved, the Licensee shall promptly store the skin tissue upon the completion of the cryopreservation process and take measures to prevent temperature fluctuation during the transfer between the freezing equipment and the storage equipment to ensure that the integrity of the skin tissue is maintained for its intended use.

5 Storage of skin tissue (Regulation 20 of HTBS Regulations)

- 5.1. The Licensee shall store processed skin tissue at the following temperatures:
 - (a) above 0°C to 10°C for refrigerated skin tissue; or
 - (b) -40°C or below for frozen or cryopreserved skin tissue.

6 Suitability of skin 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 skin tissue is distributed for transplantation.
- 6.2. Fresh or cryopreserved skin shall not be used or distributed for transplantation if any one of the following is present in any of the final packaging cultures:
 - (a) *Staphylococcus aureus*;
 - (b) *Streptococcus pyogenes* (group A strep.);
 - (c) *Enterococcus* sp;
 - (d) gram-negative bacilli;
 - (e) *Clostridium*; and
 - (f) fungi (yeasts, molds).

7 Return of skin tissue (Regulation 26 of HTBS Regulations)

- 7.1. The Licensee may return refrigerated skin tissue to its tissue bank inventory if the skin tissue has been maintained at a temperature between above 0°C to 10°C in a closed container while outside of the inventory.
- 7.2. The Licensee shall not return frozen or cryopreserved skin tissue to its tissue bank inventory where it has been thawed.
- 7.3. The Licensee shall not assign skin tissue to another patient for use where the final packaging has been opened.