

LICENCE CONDITIONS FOR
HUMAN TISSUE BANKING SERVICE LICENSEES
PROVIDING OR INTENDING TO PROVIDE
BANKING OF HAEMATOPOIETIC STEM CELL (INCLUDING BONE MARROW)
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 banking of haematopoietic stem cell (including bone marrow)

(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 haematopoietic stem cell (including bone marrow)" means the handling, processing, testing, storage and distribution of haematopoietic stem cell (including bone marrow);
- (b) "Entity" means a person that have been licensed under the HCSA to provide acute hospital service or ambulatory surgical centre service;

- (c) “haematopoietic stem cell (including bone marrow)” means stem cell capable of maturation into any of the haematopoietic lineages, regardless of tissue source (for example, bone marrow, peripheral blood, or other tissue sources);
- (d) “HTBS Regulations” means the Healthcare Services (Human Tissue Banking Service) Regulations 2023;
- (e) “Retrieving Entity” means an Entity that retrieves samples containing haematopoietic stem cell (including bone marrow) from a donor; and
- (f) “Receiving Entity” means the Entity which receives haematopoietic stem cell (including bone marrow) from Licensees for clinical use.

3. Evaluation and screening of donors (Regulation 17 of HTBS Regulations)

Requirements for haematopoietic stem cell (including bone marrow) stored for allogenic use

- 3.1. Before the Licensee stores haematopoietic stem cell (including bone marrow) from a Retrieving Entity for allogenic use, the Licensee shall ensure that the Retrieving Entity has fulfilled all requirements for evaluating the medical fitness and suitability of every donor. Such requirements shall include, but are not limited to, the Retrieving Entity having performed the following:
 - (a) an examination of the risk factors of the donor that might result in disease transmission and compatibility with the recipient;
 - (b) blood group ABO and Rhesus(D) type testing on the donor;
 - (c) testing of Human Immunodeficiency Virus (HIV) infection of the donor;
 - (d) testing of Hepatitis B and C infection for the donor;
 - (e) testing of Syphilis for the donor;
 - (f) testing of Cytomegalovirus for the donor;
 - (g) any other tests required to assess the possibility of the donor’s transmission of other infections; and
 - (h) full Human Leukocyte Antigen (HLA) typing for the donor.

4. Suitability of proposed recipient (Regulation 10(1)(a) of HTBS Regulations)

Requirements for haematopoietic stem cell (including bone marrow) distributed for allogenic use

- 4.1. Before the distribution of haematopoietic stem cell (including bone marrow) which have been processed and stored by the Licensee, to a Receiving Entity for the Receiving Entity’s allogenic use in treatment, the Licensee shall ensure that the Receiving Entity has fulfilled all requirements for evaluating the suitability of the proposed recipient of the haematopoietic stem cell (including bone marrow). Such requirements shall include, but are not limited to, the Receiving Entity having performed the following:
 - (a) blood group ABO and Rhesus(D) type testing on the recipient;
 - (b) testing of red cell antibody of the recipient; and
 - (c) full Human Leukocyte Antigen (HLA) typing for the recipient.