Directions given under the Human Tissue Act 2004 implementing the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)

Directions relating to licenses granted under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)	**Ref 001/2021**
These Directions are:	General Directions
Section of the Human Tissue Act 2004 providing for these Directions:	Sections 23
These Directions come into force on:	1 January 2021
These Directions remain in force until:	Directions are revoked by the HTA

1. These Directions are given in relation to Human Tissue Authority (HTA) licenses issued to establishments storing and importing tissues and/or cells for human application under Regulations 7(1) and 7(1A) of the Human Tissue (Quality and Safety for Human Application) Regulations) 2007(as amended) and licenses and / or third party agreements authorising the carrying out of procurement, testing, processing, distribution, import or export of tissues and/ or cells for human application under Regulation 7(2) of the Regulations.

2. The Directions are made for the purpose of securing adherence to the standards required under the Human Tissue (Quality and Safety for Human Application) Regulations) 2007 (as amended).

Implementation of the Guide for Quality and Safety Assurance for Human Tissue and Cells for Patient Treatment

3. These Directions implement the HTA consolidated requirements for human application licenses and third-party agreements. The requirements are set out in version 3 of the “Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment” which forms the Annex to these Directions. The Guide will be the primary reference for establishments and will be subject to periodic updates.

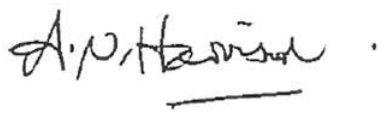
Revocation of the HTA Directions 002/2018

4. Version 3 of the Guide replaces a version issues previously under HTA Directions for the sector. Directions 002/2018 are therefore no longer required and are revoked.

5. These Directions are made by the Human Tissue Authority.

Dated: 1 January 2021

Signed:



Nicolette Harrison
Director of Regulation