



**HTA**

Human Tissue Authority

**Licensing the procurement of  
Tissues and Cells for Human  
Application**

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# Licensing under Quality & Safety Regulations 2007

- The Regulations require the following activities to be licensed or carried out under a 3<sup>rd</sup> party agreement
  - Procurement
  - Testing
  - Processing
  - Distribution
  - Import / Export
- Storage needs to be carried out under a licence

# Third Party Agreements

Written agreement between a licensed establishment and another party who:

- Carries on a licensed activity (other than storage), **on behalf of** the licensed establishment,
- Supplies to the licensed establishment any goods or services which may affect the quality or safety of tissue or cells

# Procurement

- 'A process by which tissues and cells are made available'.

Includes:

- Consent
- Donor selection & evaluation
- Removal of tissues and cells

# Procurement

- No person shall procure tissues and/or cells for human application except in accordance with Directions given by the HTA.
- The licence holder of a procurement organisation must comply with the requirements for notification of serious adverse events and serious adverse reactions

# Consent

- Prior to removal, an authorised person from the establishment must confirm and record:
  - that consent has been obtained in accordance with the Regulations and HTA Directions and
  - how and by whom the donor has been reliably identified.
- The establishment shall ensure that all **necessary information** has been given to a prospective donor.

# Consent – ‘necessary information’

- the purpose and nature of the donation,
- its consequence and risks,
- any analytical tests if they are to be performed,
- recording and protection of donor data and medical confidentiality, and
- therapeutic purpose and potential benefits of the donation.

# Donor selection and evaluation

- The prospective donor has received all necessary information
- No pressure, coercion or undue influence is or has been applied to the prospective donor
- All appropriate screening tests and the selection have been performed, complied with and are recorded.
- Donors will undergo the required biological tests

# Donor selection and evaluation of allogeneic donors

- An authorised person must collect and record the donor's relevant medical and behavioural information
- The complete donor records must be reviewed and assessed for suitability and signed by a qualified health professional.

# Donor selection and evaluation of allogeneic donors (cont'd)

- Allogeneic living donors must be selected on the basis of their health and medical history, provided on a questionnaire and through an interview performed by a qualified and trained healthcare professional with the donor.

# Autologous living donor

- If the removed tissues and cells are to be stored or cultured, the same minimum set of biological testing requirements must apply as for an allogeneic living donor.

# Laboratory tests required for donors

<b>HIV 1 and 2</b>	<b>Anti-HIV-1,2</b>
<b>Hepatitis B</b>	<b>HBsAg Anti HBc</b>
<b>Hepatitis C</b>	<b>Anti-HCV-Ab</b>
<b>Syphilis</b>	

# Removal

- Procurement shall be carried out by personnel who have successfully completed a training programme as agreed with the Designated Individual. The competence of the trained personnel shall be recorded and retained.
- The establishment shall have written agreements with the staff or clinical teams responsible for procurement.

# Removal

- Tissue and / or cell removal shall take place in facilities which are appropriate and fit for purpose and following procedures that minimise bacterial or other contamination.

# Processing - definition

- ‘...all operations involved in the preparation, manipulation, preservation and packaging of tissues and cells intended for human application’.

# Storage

- Maintaining tissues and cells, whether by preservation or in any other way, for more than 48 hours.
- European coding system

# Distribution

- ‘...transportation and delivery of tissues and/ or cells intended for human application’

## Regulation 5(4)(a)

- ‘...a person who, from any premises, controls the provision of services for transporting tissues and cells is taken to distribute tissues and cells on the premises’.
- Packaging and labelling requirements

# Import & Export of tissues and cells

- Imports (non-EEA) must meet the standards of quality and safety set out in the Directives, the Regulations, and Directions (004/2007)
- Establishments that export human tissues and/or cells must ensure that such exports comply with the Directives, the Regulations, and Directions (004/2007).



# HTA

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