HFEA and HTA Joint statement on ovarian and testicular tissue storage

The Human Fertilisation and Embryology Authority (HFEA) and the Human Tissue Authority (HTA) have been working together to reduce the regulatory overlap regarding the storage of ovarian and testicular tissue.

The legislation

**HFEA:** Following amendments to the Human Fertilisation and Embryology Act 1990 (HFE Act) which came into effect in 2009, the definition of gametes was extended to include germ line cells at any stage of maturity. Prior to this amendment only mature gametes fell within the HFEA’s remit.

**HTA:** The Human Tissue (Quality and Safety for Human Application) Regulations 2007 require establishments storing tissue or cells intended for human application to do so under the authority of an HTA licence. Tissue is defined in the regulations as ‘all constituent parts of the human body formed by cells’. This definition would include ovarian or testicular tissue for use in transplant.

A consequence of the amendment to HFE Act is that establishments storing tissue containing immature gametes now require a licence from the HFEA and the HTA if the tissue containing the gametes is being stored for future transplant into a recipient, or where the intended future use of the tissue is unknown.

In order to minimise the impact of the regulatory overlap created by the amendment the HFEA has decided to exercise its discretion in relation to the application of the amended definition so that appropriate regulation is applied according to the intended use of the tissue.

What this means in practice

**Tissue intended for fertility treatment**

Any centre with an HFEA licence for storage may cryopreserve and store ovarian or testicular tissue for future use in fertility treatment

In this scenario, the statutory storage periods that apply to the storage of gametes also apply to the storage of testicular and ovarian tissue: storage for a maximum of 10 years unless a registered medical practitioner has given a written opinion that the patient (or the person to be treated) is prematurely infertile or is likely to become prematurely infertile. It would be a matter for a clinician to decide if the removal of ovarian or testicular tissue for cryopreservation would render an individual likely to become prematurely infertile. If this condition is satisfied, centres may store material for a maximum of 55 years.
The Grade C air quality requirements for processing of gametes will also apply (as required by HFEA standard licence condition T20). However, if the intended use of the tissue (processed in Grade C air quality) was to change, it may not be considered suitable for future transplant, as a higher grade of air is required for processing tissues intended for transplantation.

**Tissue intended for transplantation**
Where a centre wishes to store ovarian or testicular tissue for transplantation, the centre must have an HTA licence. The processing of the tissue must be carried out in compliance with the Human Tissue (Quality and Safety for Human Application) Regulations 2007; detailed standards are set out in the Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment, which was brought into effect through HTA Directions 003/2010. This includes processing in air of Grade A quality as defined in the current European Guide to Good Manufacturing Practice (GMP), Annex 1 of Directive 2003/94/EC (as required in paragraph 52 of the Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment).

Prior to processing ovarian tissue or testicular tissue, establishments must submit a Preparation Process Dossier to the HTA for authorisation.

In this situation, the centre will no longer need an HFEA licence to store the tissue.

**Tissue where the intended use is uncertain**
Where a centre is uncertain at the time of storage whether the tissue will be used in fertility treatment or for transplantation, or where the intended use of the tissue changes, the tissue can remain in storage in either an HFEA- or HTA-licensed centre until the intended use of the tissue is determined. When a decision is reached about the intended use of the tissue, it should be transferred to an appropriately licensed (HFEA or HTA) facility. We strongly recommend that if there is a possibility that tissue may be used for transplant, it should be processed according to HTA standards from the outset.

This policy applies to transplantation of patients’ own tissue (autologous use) only. If transplant technology develops, to make transplantation of donor tissue possible, we will revisit this policy position to ensure appropriate collection and provision of donor information.

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1 Transplant of ovarian or testicular tissue refers to the re-implantation, for purposes such as the restoration of hormonal balance and/or fertility for example, of stored tissue which contains gametes; rather than the use of the tissue as a source of gametes that can be matured in vitro for use in assisted reproduction.